Imperial Oil and Gas

EP 187

Appendix 08

Human Health and Environmental Risk Assessment

IMP 5-1

Human Health and Environmental Risk Assessment for Carpentaria Gas Project

Imperial Oil & Gas and Imperial Oil and Gas A Northern Territory Tenement

Prepared for:

INGAUGE
Well Engineering & Project Management
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EHS Support

January 2024

Document Control

PROJECT DETAILS

Project No.	PTY.04921.0000
Report Revision No.	3
Date of Issue	22/01/2024
Project Manager	Joe Hayes
Project Director	Nigel Goulding

REPORT DETAILS

Title	Human Health and Environmental Risk Assessment for Carpentaria Gas Project
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DISTRIBUTION LIST

Date	No. of Copies	Company/Organisation	Name	Issue Type
17/01/2024	1	inGauge Energy Australia	Trent Smith	e

Note:
(e) electronic file
(h) hardcopy

REVISION HISTORY

Date	Revision #	Status / Summary of Key Changes
21/12/2021	A	Draft for client review
27/01/2022	B	Draft for client review
04/02/2022	0	Final
14/04/2023	1	Minor corrections in response to regulator comments. Added revision history and corrected revision numbers.
31/10/2023	2	Updated title of report, incorporate summary information on human health evaluation as Table 2 in text, revision to Appendix B (V-Leach model)
22/01/2024	3	Removal of poly(tetrafluoroethylene) from evaluations.

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Table of Contents

1 Introduction **1**

2 Tier Assessment **6**

2.1 Conceptual Exposure Model 6
2.2 Tier 1 Assessment 8
2.3 Tier 2 Assessment 10
2.3.1 Worker 10
2.3.2 Avian Wildlife 11

3 Summary and Risk Management **12**

4 Limitations **13**

5 References **14**

List of Tables

Table 1 Evaluation of Compiled List of Chemicals
Table 2 Summary of Human Health Assessment

List of Figures

Figure 1-1 Location of Imperial and Imperial A Tenements
Figure 1-2 Eastern (Imperial) Tenements and Geological Basins
Figure 1-3 Western (Imperial A) Tenements and Geological Basins

List of Appendices

Appendix A Compiled List of Chemicals
Appendix A.1 Compiled List of March 2020 Chemicals
Appendix A.2 Compiled List of May 2021 Chemicals
Appendix A.3 Compiled List of January 2022 Chemicals
Appendix B Potential Risk to Groundwater from Hypothetical Water Releases
Appendix C Risk Dossiers
Appendix C.1 March 2020 Risk Dossiers
Appendix C.2 May 2021 Risk Dossiers
Appendix C.3 January 2022 Risk Dossiers
Appendix D Safety Data Sheets
Appendix D.1 March 2020 Safety Data Sheets
Appendix D.2 May 2021 Safety Data Sheets
Appendix D.3 January 2022 Safety Data Sheets
Appendix E Tier 2 Assessment – Worker
Appendix F Tier 2 Assessment – Avian Wildlife

Acronyms

AICIS	Australian Industrial Chemicals Introduction Scheme, 2022
bw	body weight
CAS	Chemical Abstracts Service
COPC	constituent of potential concern
DoEE	Department of the Environment and Energy
EMP	Environment Management Plan Imperial 2020 Drilling Program NT EP187
EP	Exploration Permit
LC50/EC50	lethal concentration 50 / effect concentration 50
MoE	Margin of Exposure
NEPC	National Environment Protection Council
NEPM	National Environment Protection (Assessment of Site Contamination) Measure
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NT	Northern Territory
PBT	persistent (P), bioaccumulative (B) and toxic (T)
SDS	safety data sheet

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Units of Measure

Area	
ha	hectare
m^2	square metres
Density	
kg/m^3	kilograms per cubic metre
Electrical Conductance	
µS/cm	microsiemen per centimetre
dS/m	decisiemen per metre
mS/cm	millisiemen per centimetre
mV	millivolt
Length	
µm	micrometres
cm	centimetres
km	kilometres
m	metres
mm	millimetres
Mass	
µg	micrograms
g	grams
kg	kilograms
mg	milligrams
t	metric tonnes
Concentration by Mass	
µg/kg	microgram per kilogram
mg/kg	milligram per kilogram
Pressure	
kPa	Kilopascals
Pa	Pascals
Temperature	
°C	degrees Celsius
°F	degrees Fahrenheit
K	Kelvin
Velocity	
m/s	metres per second

Volume	
µL	microlitres
cL	centilitres
cm^3	cubic centimetre
GL	gigalitre
L	litres
m^3	cubic metre
mL	millilitres
ML	megalitre
Concentration by Volume	
µg/L	microgram per litre
mg/L	milligram per litre
ppmv	parts per million by volume
ppbv	parts per billion by volume

1 Introduction

Imperial Oil & Gas and Imperial Oil & Gas A (for the purpose of this report referred to as "Imperial" and "Imperial A" respectively) operate petroleum tenements in the Northern Territory (NT) within a number of basins (see **Figure 1-1**). Imperial and Imperial A are progressing exploration activities across their respective tenements, including undertaking seismic surveys, drilling targeted exploration wells and subsequent hydraulic fracturing of these wells. inGauge Energy Australia ("inGauge"), acting for Imperial and Imperial A, has been supporting their program and has prepared an Environment Management Plan (EMP) for Imperial's 2021 Hydraulic Fracturing Program NT Exploration Permit (EP) 187 (inGauge 2021) and subsequently and EMP for Imperial's 2021-2025 EP187 Drilling Program (inGauge 2021) (which also covers stimulation activities). Imperial and Imperial A are expanding outside of EP187, and inGauge is progressively extending EMPs across Imperial and Imperial A's other tenements in the NT as exploration programs are developed. At this stage, EMPs have also been developed for EP167 and EP168.

Under the Code of Practice: Petroleum Activities in the Northern Territory 2019 (the Code), an EMP is required for oil and gas activities. Hydraulic stimulation (or fracturing) activities were reviewed in the "Independent Scientific Inquiry into Hydraulic Fracturing of Onshore Unconventional Reservoirs in the Northern Territory" report issued on 27 March 2018 (NT, 2018). The Inquiry concluded that the risks associated with unconventional onshore shale gas extraction in the NT could be appropriately managed provided all the recommendations of its report were adopted and implemented. The NT Government accepted all 135 recommendations and announced the lifting of a previous moratorium on exploration on 17 April 2018. Of the 135 recommendations, 35 were required to be implemented prior to the commencement of exploration, with the remaining recommendations required to be implemented prior to the commencement of production. The development of an EMP is a key component of meeting these requirements. The EMP documents the relevant natural environment, proposed activities and methods to manage the environmental impacts and risks associated with proposed activities, including how to address regulatory obligations and relevant report recommendations that have underpinned the Code of Practice: Onshore Petroleum Activities in Northern Territory 2019.

Imperial has been drilling in EP187, which is located within the Carpentaria and McArthur Basins, for which the EMPs noted above have been developed. These EMPs include specific reference to hydraulic stimulation (inGauge 2021), which includes a hydraulic stimulation chemical risk assessment (CRA) (EHS Support, 2021). The CRA was prepared specifically for that tenement, and at the time the report was issued, two wells within the tenement have been drilled and either stimulated or planned to be stimulated (i.e. Carpentaria 1 and Carpentaria 2, respectively[1]). Imperial and Imperial A are now planning exploration activities, including drilling wells and undertaking hydraulic stimulation within its other tenement across the NT, which are grouped for the purpose of this report as the Eastern (Imperial tenement) and Western (Imperial A tenement), in **Figure 1-2** and **Figure 1-3**, respectively.

inGauge Energy ("inGauge") has been undertaking planning for the drilling and the hydraulic stimulation program across all of Imperials NT tenements and has retained EHS Support Pty Ltd ("EHS Support") to prepare and then update the CRA to better reflect the existing and proposed exploration tenements and stimulation fluids. Additionally, the CRA was updated to address the Petroleum (Environment) Regulations 2016, as in force at 22 June 2023 (NT, 2023), requirement to perform a full human health risk assessment. An assessment of human health risks was performed as part of the

[1] As of 31/10/2023, Carpentaria 1, 2 and 3 have all been stimulated.

previous CRAs; however, a summary of information specific to human health hazards was not included. This Human Health and Environmental Risk Assessment (HHERA) documents the relevant EMP requirements utilising the chemicals present in the hydraulic stimulation formulations historically utilised or proposed in EP187 (EHS Support 2021) as well as the updated formulation proposed for future stimulation activities. The chemicals within these formulations have been specifically referred to within this HHERA using the following:

- March 2020
- May 2021
- January 2022

These three formulations are presented in tables in **Appendix A** and this HHERA includes evaluation of all three fluid systems, with the exception of poly(tetrafluoroethylene) that is listed in the May 2021 and January 2022 formulations. It was decided not to use the product containing this chemical for stimulation activities. Therefore, this chemical will not be evaluated in the HHERA even though it is shown in **Appendix A**. Additional updates to this HHERA are possible in the future, with the evaluation of any additional proposed chemicals/revised chemical concentrations, and this will be undertaken where applicable.

This HHERA and any update will follow the tiered risk evaluation approach presented in the EP187 CRA. The overall chemical risk assessment methodology, results, and conclusions are applicable to other Imperial and Imperial A tenements that have the same conceptual exposure model, including environmental setting, hydrogeology/geology, the lifecycle of chemicals and potentially complete exposure pathways.

This assessment evaluates potential hazards associated with chemicals and the potential for human and environmental receptor exposure, and where potentially hazardous chemicals have complete exposure pathways, quantification of the potential risks. This chemical risk assessment is supported by a broader evaluation of environmental conditions and risks and recommended avoidance, mitigation and management strategies.

This chemical risk assessment for the hydraulic stimulation activities developed as part of the EMPs meets the requirements of the NT Code of Practice as well as being in general accordance with the following:

- NT Government, Department of Environmental and Natural Resources, Draft Guideline for the Preparation of an Environmental Management Plan under the Petroleum (Environment) Regulations (NT, 2023);
- Department of the Environment and Energy, Exposure Draft - Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction (DoEE, 2017);
- Australian Industrial Chemicals Introduction Scheme, 2022 (AICIS) (which has progressively replaced NICNAS below, since 31 August 2020)
- National Industrial Chemicals Notification and Assessment Scheme (NICNAS), National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia (NICNAS, 2017a);
- enHealth Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards (enHealth, 2012); and
- National Environment Protection (Assessment of Site Contamination) Measure 1999 (ASC NEPM); Schedule B4, Site-specific health risk assessment methodology (NEPC, 2013).

Reference has also been made to the relevant information available within the Northern Territory Governments "POINT" online mapping and data catalogue and the Australian Governments, Geological and Bioregional Assessment for the Beetaloo GBA (where appropriate).

The chemicals assessed in this HHERA have been compiled from several formulations that have been used (or are planned for use) in the Beetaloo Sub-Basin and potentially in other tenements and basins. The lists of chemicals assessed are presented in **Appendix A** (Table A1 from March 2020; Table A2 from May 2021; Table A3 from January 2022) and were provided by inGauge and includes research undertaken on maximum concentrations that potentially would be used in a hydraulic stimulation. It should be noted that the compiled lists of chemicals have been assessed as "one formulation" (noting that they contain a number of separately used components that are applied at various stages during the stimulation process) with maximum concentrations provided by inGauge. This is a conservative assessment for the hydraulic stimulation program because the actual concentration of individual chemicals will likely be less, and there will be fewer chemicals represented in a selected formulation.

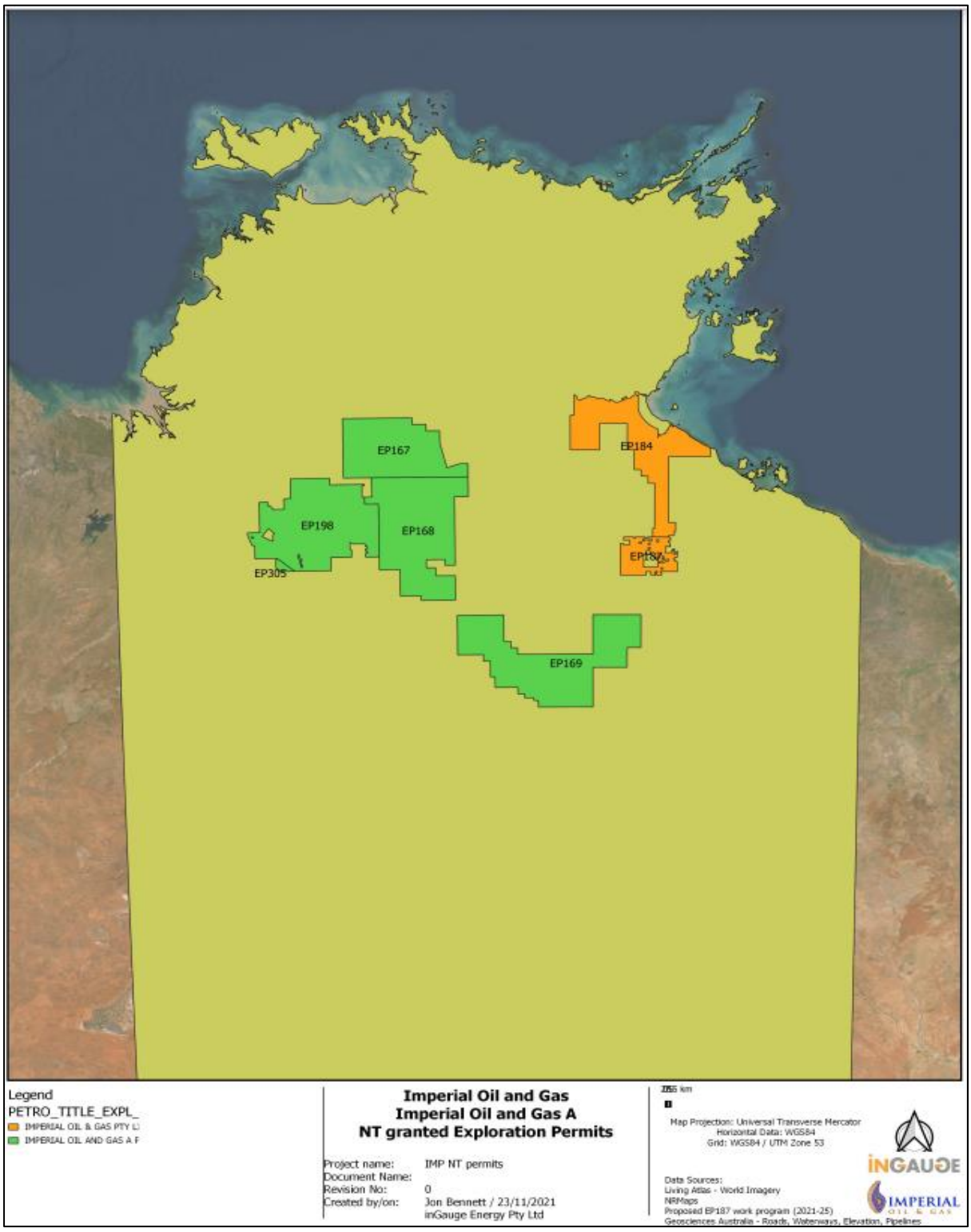


Figure 1-1 Location of Imperial and Imperial A Tenements

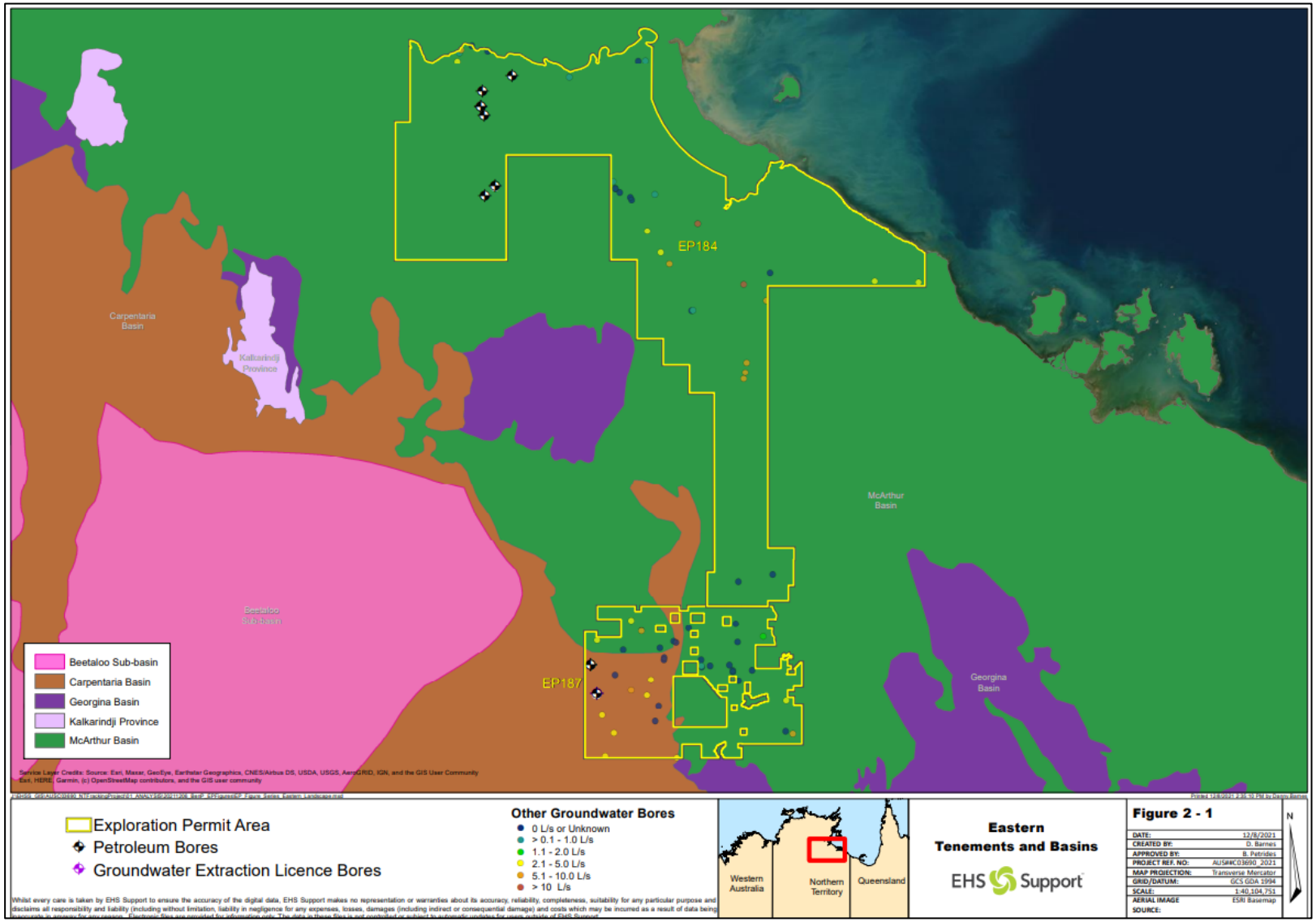


Figure 1-2 Eastern (Imperial) Tenements (EP184 and EP187) and Geological Basins

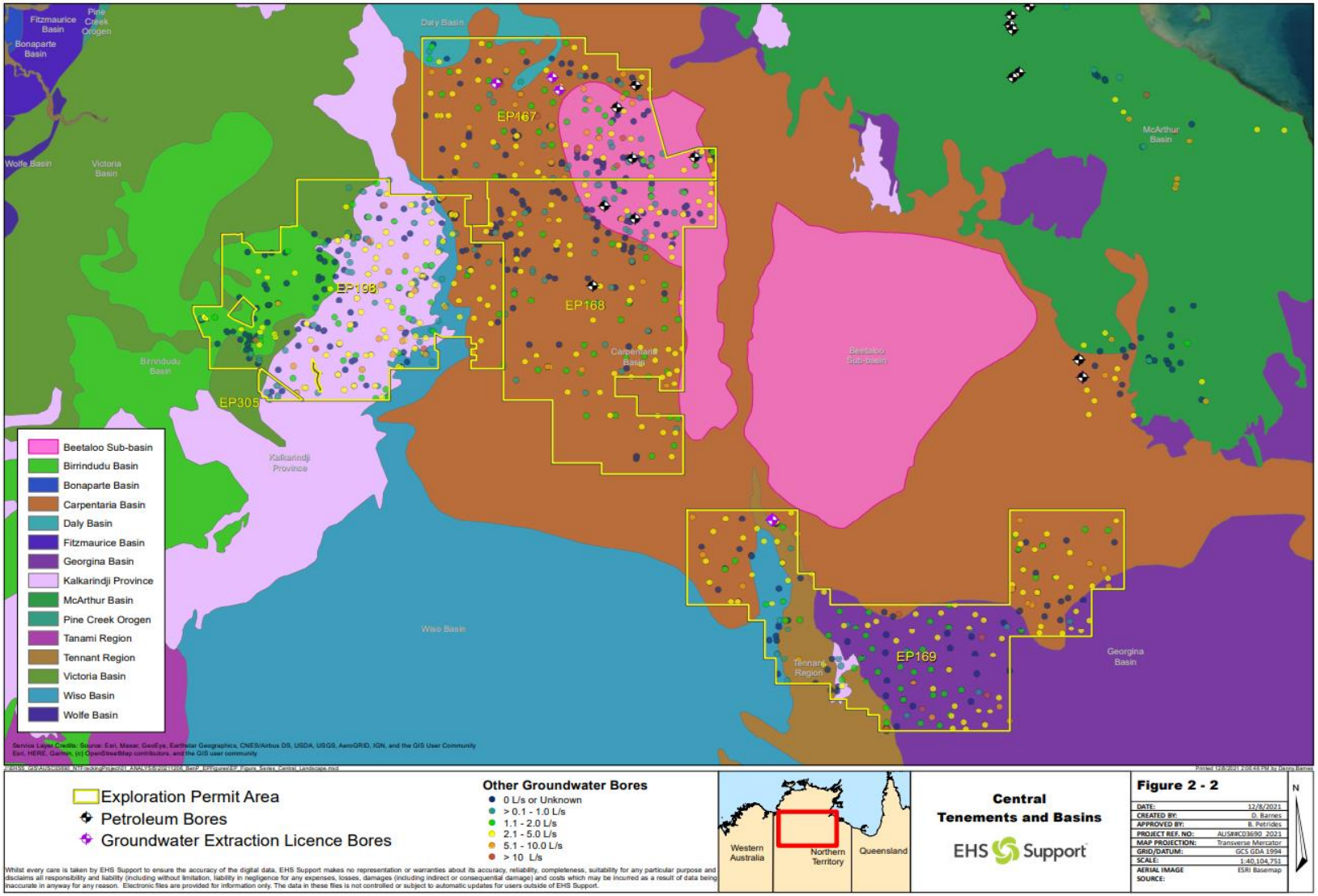


Figure 1-3 Western (Imperial A) Tenements (EP167-9, EP198 and EP305) and Geological Basins

2 Tier Assessment

A tiered assessment was conducted on the compiled hydraulic fracturing fluid systems using screening of the potential human health and ecological hazards that should be considered for potential exposure to the hydraulic fracturing fluids during transportation, hydraulic fracturing activities (including storage), and subsequent treatment and disposal of flowback. The tier assessment includes the following steps:

- Tier 1 – Identify chemicals of low human health and ecological concern that do not require additional chemical risk assessment in the tier assessment process.
- Tier 2 – Chemicals that are not identified as a low human health and ecological concern and therefore require an additional risk assessment to characterise potential risks. This is done using a quantitative evaluation of the risks based on the potential complete exposure pathways and Tier 1 assessment.

The assessment followed the methodology and guidance presented in the following:

- Northern Territory Government, Department of Environmental and Natural Resources, Draft Guideline for the Preparation of an EMP under the Petroleum (Environment) Regulations (NT, 2023) (herein referred to as NT 2023);
- Department of the Environment and Energy, Exposure Draft - Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction (DoEE, 2017) (herein referred to as DoEE 2017);
- NICNAS, National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia (NICNAS, 2017a);
- enHealth “Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards” (enHealth, 2012); and
- National Environment Protection (Assessment of Site Contamination) Measure 1999 (ASC NEPM); Schedule B4, Site-specific health risk assessment methodology (NEPC, 2013).
- Environmental risk assessment guidance manual for industrial chemicals (NEPC, 2009)

2.1 Conceptual Exposure Model

The EMP developed for EP187 for the 2021-25 work program (inGauge, 2021) provides an overview of the proposed hydraulic stimulation program, which is similar to that which will be utilised on Imperials other NT tenements. The stimulation process involves pumping slurry, primarily consisting of water and sand (proppant) plus a minor volume of a specific blend of chemicals down the well to a specific geological target at sufficient pressure to create a fracture in the target geological formation. Proppant keeps the fractures open once the pump pressure is released, thereby improving the wells productive potential. Chemicals used in hydraulic stimulation fluid systems are designed to optimise stimulation outcomes and are commonly found in food and other household domestic products.

There are several techniques for hydraulic fracture stimulation. The two more viable methods to be implemented by Imperial and Imperial A are Plug and Perf, and coiled tubing assisted annular stimulation. Plug and Perf is commonly implemented in wells with cemented liners and consists of pumping down a bridge plug on a wireline with perforating guns to a given horizontal location near the toe of the well. The plug is set, and the zone is perforated. The tools are then removed from the well, and the fracture stimulation treatment is pumped in. The set plug or ball-activated plug then diverts fracture fluids through the perforations into the formation. The stage is completed, the next

plug and perforations are initiated, and the process is repeated, moving back to the heel of the well. The coiled tubing method is used to provide a conduit for "pinpoint fracturing". Coiled tubing is run into the well to the deepest target. The bottom-hole assembly run on the end of the coiled tubing incorporates a jetting assembly that allows low concentration sand slurry to cut holes or slots into the casing and cement. The hydraulic stimulation treatment is then pumped into the coiled tubing/casing annulus to initiate and propagate the fracture.

Both of these techniques for fracture stimulation can take approximately 5 to 40 days per well, depending on the number of zones perforated. The hydraulic stimulation technique will be confirmed once the drilling program has been completed and well conditions are assessed.

The life cycle of chemicals used during the hydraulic fracturing of wells includes the following general categories:

- Transportation of chemicals – from the supplier warehouse to the well lease and between well leases
- Hydraulic fracturing activities – storage of chemicals, usage (e.g., blending, injecting) and subsequent recovery of fluids (including storage in produced water and flowback fluid treatment tanks) at the well lease and associated vendor chemical additives
- Disposal and management – recovered vendor chemical additives in wastes and hydraulic fracturing flowback.

Throughout the life cycle of chemical additive products, without adequate management controls in place, there is the potential for human and environmental receptors to be exposed to the chemical additives. Based on an evaluation of the life cycle of products and chemicals, environmental conditions in the areas of development, anticipated populations and location selection, the following potentially complete exposure pathways were identified:

- Transportation of chemicals:
  - Human and environmental receptor exposure to chemicals as a result of accidental release during transport from supplier warehouse to well lease or between well leases (i.e., truck rollover).
  - Human and environmental receptors exposed to surface water bodies that received runoff from an accidental release during transportation.
- Hydraulic fracturing activities:
  - Human and environmental receptor exposure to chemicals as a result of accidental release during the storage and preparation of products on the well lease for hydraulic fracturing activities.
  - Human and environmental receptor exposure to residual chemicals (vendor chemicals) in recovered materials as a result of an accidental release from storages (treatment tanks) on the well lease.
  - Human and environmental receptors exposed to surface water bodies that received runoff from an accidental release during hydraulic fracturing activities.
- Treatment and disposal:
  - Human and environmental receptor exposure to chemicals as a result of accidental release during transport of surplus chemicals and wastes (i.e., flowback) from the well lease to a disposal/management facility.
  - Human and environmental receptor exposure to chemicals as a result of accidental release of stored wastes and/or flowback.
  - Human and environmental receptors exposed to surface water bodies that received runoff from an accidental release of stored wastes and/or flowback.

To assess the unmitigated risks from the improbable scenario where some fluids were to overflow the bunded area, a range of release scenarios are considered comprising:

- Smaller release volumes of 1,000 L and 100,000 L which would reflect small scale releases, and
- An improbable release out of the bunded area (1,000,000 L).

Appendix B provides an assessment of the potential for effects on groundwater associated with a release of hydraulic fracturing fluid, waste or flowback to the land surface scenarios. The results of this assessment, undated to include the additional NT tenements of Imperial and Imperial A, showed the travel times for surface releases to reach groundwater are very long, thereby providing ample opportunity for containment and remedial action. Therefore, the potential for impacts to groundwater is considered low.

Both mitigated and unmitigated risks from an overland flow scenario from a release have been assessed as part of the assessment. inGauge has proposed to construct a 2 ha well pad, with 0.5 m high berm walls surrounding any inground treatment tanks and/or double-lined aboveground tanks to contain and manage the risk from potential releases. In the absence of this structure, a major release could have the potential to migrate a distance off the well pad. However, with these measures, any releases would be limited to the potential for incidental/minor spillage outside the fluid storage and containment area. In the context of a potential release scenario of 100,000 L outside of the containment and storage area, the maximum affected area of spreading will be less than 4.7 ha and limited to the proximity of the release area.

Therefore, given the planned management control of the construction of a bunded area surrounding treatment tanks, the potential for a complete exposure pathway to surface water bodies associated with runoff from an accidental release is considered unlikely and not assessed further.

The risks associated with the transport of chemicals and wastes is considered to be managed to a level as low as reasonably practicable. This is because the potential for a release is controlled through the implementation of a traffic management plan (including use of designated trucking routes, vehicle signage, vehicle management systems (to manage speed and driving behaviour/habits). In the unlikely event of a vehicular accident, incident and spill response procedures will be implemented. In this context, this scenario is not assessed further.

The management of chemicals and wastes will be conducted at the well lease using drums, intermediate bulk containers and engineered tanks designed to contain the fluids. No permanent storage of chemicals, flowback or wastes will be conducted in ponds or sumps, and therefore the potential for releases is considered limited. Wastewater will be managed through the use of engineered treatment tanks that will contain liquids and may have the potential for exposures to avian receptors; however, this exposure route is unlikely given the salinity of the water. In the unlikely event of a release to the ground, the potential for exposures (other than workers) is limited. The well pad sites are fenced to limit access to the public and prevent entry by livestock and large native fauna. If materials are spilled to the ground, then investigation, remediation and rehabilitation activities will be immediately implemented to address soil impacts. In this context, exposure during and post-activity are unlikely.

Lastly, chemical exposures to workers are controlled through engineering, management controls and personal protective equipment, which are focused on elimination and mitigation of the potential for dermal contact and potential for incidental ingestion (therefore, the exposures are considered

unlikely). Respiratory protection may not always be standard on hydraulic fracturing worksites, so this is considered a potential complete exposure pathway for volatile constituents.

2.2 Tier 1 Assessment

The Tier 1 assessment includes an evaluation of the human health and environmental hazards of the chemicals in the two hydraulic fracturing fluid systems. The objective of the Tier 1 assessment is to identify chemicals of low human health and ecological concern that do not require additional chemical risk assessment in the Tier 2 assessment. A persistent, bioaccumulative and toxic (PBT) assessment was conducted because of specific concerns for substances that can be shown to persist for long periods in the environment, bioaccumulate in food chains, and that can give rise to toxic effects after a longer time and over a greater spatial scale than chemicals without these properties.

Further, a regulatory review was conducted to determine if the chemicals were identified as potential chemicals of concern in the Australian NICNAS. Additional information is provided in the risk assessment dossiers (**Appendix C**) and safety data sheets (SDSs) (**Appendix D**) for the compiled hydraulic fracturing fluid systems. This information can be used for emergency responders, health and safety managers and environmental hazard clean-up teams.

As per the NT Government Guidance (NT 2019), the Tier 1 assessment included the following:

- Name of chemical;
- Chemical purpose;
- Chemical Abstract Service (CAS) number;
- Total mass in kg;
- Approximate downhole concentration for that chemical expressed in mg/L;
- Appropriate ecotoxicity (aquatic and oral values) data including for acute lethal concentration 50 / effect concentration 50 (LC50/EC50) and chronic no observed effect concentration (NOEC) data where available; and
- Information on the biodegradation and bioaccumulation potential of organic chemicals.

The results of the Tier 1 assessment for the hydraulic fracturing fluid system formulations noting which chemical additives were assessed, the information used for the assessment, and the chemicals categorised as Tier 1 or Tier 2, is presented in **Table 1**, attached. **Table 2**, below, includes a summary of relevant information for the human health assessment in addition to the summary in **Table 1**, attached, and chemical dossiers (**Appendix C**). Discussion is provided in **Table 1**, attached, on the Tier 1 assessment findings as to whether a chemical was retained for further evaluation in the Tier 2 assessment. Observed recovery of drilling, well development, and hydraulic fracturing fluids chemicals in flowback from other regional operators of Oil and Gas petroleum tenements is approximately 20 percent or less of the injected fluid chemical concentration. The concentration declines have been attributed to dilution by pore water within the shales, sorption, complexation and decay (bio-decay, hydrolysis). For the purposes of the Tier 1 and Tier 2 assessments, the higher injected fluid concentrations have been considered.

The following general approach was used to screen the constituents of potential concern (COPCs):

- A chemical was identified by AICIS (2022) or NICNAS (NICNAS, 2017a; NICNAS, 2017b; as a chemical of low concern, and the PBT assessment did not identify a PBT substance, and no human health hazard was identified; therefore, a Tier 2 assessment was deemed not to be warranted.

- If the chemical was not categorised by NICNAS as a chemical of low concern (either because it needed further evaluation or was not included in the 2017 NICNAS assessment) but was not a PBT substance and no human health hazard was identified, then a Tier 2 assessment was deemed not to be warranted.
- If the chemical satisfied the toxicity criteria for the PBT assessment because of aquatic toxicity values or a human health hazard was identified, the potential for complete exposure pathways was then assessed to determine the potential for risk (an incomplete pathway precludes an exposure occurring and an associated potential risk). In this context, site setting and management protocols associated with the action were evaluated, and if the pathway was incomplete, a Tier 2 assessment was not deemed to be warranted. Key controls limiting the potential for exposure included:
    - Implementation of the management controls within the EMP, which ensures the well site is located away from surface water (the current location is greater than 2.5 km away from the major tributary, precluding a surface release from impacting surface water).
    - Maintenance of access control restrictions during hydraulic fracturing activities that will prevent access by the public, livestock and large native fauna.
    - Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure.

The outcome of the Tier 1 assessment identified the chemicals of low human health and environmental concern. Based on this outcome, no further management or mitigation is considered necessary for the majority of the chemicals. The following section presents the eleven (11) chemicals that could potentially pose significant hazards or risks evaluated in the Tier 2 Assessment.

Table 2 Summary of Human Health Assessment

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione	9051-89-2	1	2.18	ND	ND			Data from degradation testing according to standard methods are not available. However, there is evidence that PLA can undergo degradation via isolated and variable bacterial populations. Given the plasticine nature of the polymer and its high molecular weight, bioconcentration, bioaccumulation, and sorption are not expected to be appreciable.	NA	No
2,2"-oxydiethanol - impurity (Diethylene glycol)	111-46-6	1	0.1	5.08	16500			Readily biodegradable, up to 92% degradation after 28 days. Is not expected to bioaccumulate based on a BCF value of 100 and a log K_{ow} value of -1.98.	No recommendations as existing regulatory controls are considered sufficient.	No
2-Ethyl hexanol	104-76-7	1	0.0696	>0.89	2047			Readily biodegradable, reaching >95% degradation within five days. It is not expected to bioaccumulate based on an experimental log K_{ow} of 2.9.	NA	No
2-Propenamid (impurity)	79-06-1	1	0.0174	12	177			Found to degrade approximately 100% in 28 days. Log K_{ow} of -0.9. Not expected to bioaccumulate.	NA	UN number: 2074 (solid)
2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt	129898-01-7	1	1.49	ND	>5000			Read-across substance found to be not readily biodegradable; 20% degradation in 28 days. Not expected to bioaccumulate due to its molecular weight.	NA	No
Acetaldehyde	75-07-0	1	0.0703	24.04	660			Readily biodegradable with 80% degradation achieved after 14 days. It is not expected to bioaccumulate based on a log K_{ow} of -0.17 and a BCF value of -0.033 for upper trophic levels	NA	Transport hazard class 3; UN Number 1089
Acetic acid	64-19-7	1	66	11.4	3310			Readily biodegradable with 96% degradation after 20 days. Bioaccumulation is not expected to occur because acetic acid dissociates completely in aqueous solution to acetate and its hydrogen ion which are both ubiquitous in the environment	NA	Class 8
Acrylamide acrylate copolymer	9003-06-9	1	22	ND	ND			Not expected to be readily biodegradable and it is not expected to bioaccumulate due to its very high molecular weight and low water solubility.	Low concern polymer	No
Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer	38193-60-1	1	1	ND	>5000			No data is available. Not expected to be readily biodegradable but it is not expected to bioaccumulate due its high molecular weight and low water solubility (1000 g/L). Less than 10% biodegradation after 44 days.	Low concern polymer	No
Acrylamide, sodium acrylate copolymer	25085-02-3	1	10	ND	ND			Not expected to be readily biodegradable but it is not expected to bioaccumulate due to its very high molecular weight and low water solubility.	Polymer identified as low concern to human health by application of expert validated rules	No
Acrylamide, sodium acrylate polymer	25987-30-8	1	143	ND	ND			Not expected to be readily biodegradable and it is not expected to bioaccumulate due to its very high molecular weight and low water solubility.	Low concern polymer	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Acrylamide/ammonium acrylate copolymer	26100-47-0	1	5.78	ND	ND			Not expected to be readily biodegradable but it is not expected to bioaccumulate due to its very high molecular weight and low water solubility.	Low concern polymer	No
Acrylonitrile	107-13-1	1	0.1	1.38	72			Inherently biodegradable, reaching 61% after 14 days and 100% after 28 days. It is not expected to bioaccumulated based on a log K_{ow} of 0.017	NA	Hazard Class 3; UN Number 1093
Alcohols, C10-16, ethoxylated propoxylated	69227-22-1	1	71	>0.22	1100			Readily biodegradable. It has a low potential to bioaccumulate based on reported BCF values ranging from <5 to 387.5.	NA	No
Alcohols, C12-14-secondary, ethoxylated	84133-50-6	1	0.0615	ND	1000			Readily biodegradable, 80-88% degradation after 28 days. It has a low potential to bioaccumulate based on BCF values of <5 to 387.5	NA	No
Alcohols, C12-15, ethoxylated	68131-39-5	1	1	ND	1000			Readily biodegradable with 80-88% degradation reached within 28 days. It has a low potential for bioaccumulation based on BCF values of <5 to 387.5	NA	No
Alcohols, C12-16, ethoxylated	68551-12-2	1	1	ND	1000			Readily biodegradable with 80-88% degradation reached within 28 days. It has a low potential for bioaccumulation based on BCF values of <5 to 387.5	NA	No
Alcohols, C6-12, ethoxylated propoxylated	68937-66-6	1	199	>0.22	1100			Readily biodegradable with 63% degradation reached within 28 days. It has a low potential for bioaccumulation based on BCF values of <5 to 387.5	NA	No
Aldol	107-89-1	1	1.292	ND	2180			This substance is predicted to be readily biodegradable based on predictions from EPISUITE. It is not expected to bioaccumulate based on a log K_{ow} value of -0.722	NA	Class 6.1; Packing Group II; UN number 2839
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	1	1	ND	10000			It is readily biodegradable, 70% degradation after 28 days. It has a low potential to bioaccumulate based on a calculated BCF value of 112.53 L/kg.	NA	No
Amine oxides, cocoalkyldimethyl	61788-90-7	2	3	ND	846			Readily biodegradable, 93% degradation after 28 days. It is not expected to bioaccumulate based on a log K_{ow} value of <2.7	NA	Environmentally hazardous substances
Ammonium Chloride	12125-02-9	1	0.263	3.6	1410		Inorganic, N/A	Bioaccumulation is not expected due to this chemical's high water solubility (372 g/L) and ionic nature	NA	No
Ammonium sulfate	7783-20-2	1	1	0.0035	>2000		Inorganic, N/A	Not expected to bioaccumulate due to a log K_{ow} of -5.1	Chemical identified as low concern for human health	UN number: 20506 (Solid)
Benzaldehyde	100-52-7	1	2	ND	1300			Readily biodegradable with 100% degradation reported after 19 day. It is not expected to bioaccumulate based on a log K_{ow} value of 1.4	NA	Class 9; UN Number 1990
Bismuth Oxide	1304-76-3	1	0.0892	ND	2000		Inorganic, N/A	It is an inorganic mineral that is slightly soluble in water, thus it is not expected to be bioaccumulative	NA	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
but-2-enedioic acid (Fumaric Acid)	110-17-8	1	0.1	1306	9300			Readily biodegradable, 67.5 % biodegradation after 28 days. Low potential for bioaccumulation based on a log $K_{ow} \leq 3$	NA	No
Butyl alcohol	71-36-3	1	1	>20	2290			Readily biodegradable, 87% degradation after 10 days. It is not expected to bioaccumulate based on a log K_{ow} value of 1.0.	NA	Hazard class 3; UN Number 1120
Calcium Chloride	10043-52-4	1	1	ND	2301		Inorganic, N/A	Dissociates completely in aqueous media. Essential ions to biological systems. Neither calcium chloride or its dissociated ions are expected to bioaccumulate.	NA	No
Ceramic Materials and wares, chemicals	66402-68-4	1	1199	>2.3	>2000		Inorganic, N/A	It is not expected to biodegrade and it is not expected to bioaccumulate	NA	No
Chlorous acid, sodium salt	7758-19-2	2	0.118	ND	284		Inorganic, N/A	Chlorous acid, sodium salt readily dissolves in water to the sodium (Na^+) and chlorite (ClO_2^-) ions. The chlorite (ClO_2^-) ion is in equilibrium with chlorous acid ($HClO_2$) in water. It is not expected to bioaccumulate	NA	Class 8; Packing Group II; UN1908
Choline Chloride	67-48-1	1	1096	ND	3500			Choline chloride is readily biodegradable. Distribution modelling shows choline to completely dissolve in water.	Chemical identified as low concern for human health	No
Cinnamaldehyde	104-55-2	1	14	ND	2200			Readily biodegradable, 100% degradation after 28 days. It is not expected to bioaccumulate based on a log K_{ow} value of 2.107	NA	No
Citric acid	77-92-9	1	4	ND	5400			Readily biodegradable based on results of the ready and inherent aerobic biodegradation studies. It is not expected to bioaccumulate based on log K_{ow} values of -1.61 to -1.80	NA	No
Cocobetaine	61789-40-0	1	2.62	ND	>1500			Readily biodegradable, 100% degradation after 28 days. Has a low bioaccumulation potential based on results from a QSAR model	NA	No
Copper(II) sulfate	7758-98-7	2	0.001	ND	481		Inorganic, N/A	Natural element and transition metal that is not expected to become biomagnified	NA	UN number: 3288 (Solid)
Crontonaldehyde	123-73-9	2	0.121	0.19	174			Readily biodegradable, 55% degradation after 28 days. It is not expected to bioaccumulate based on a log K_{ow} value of 0.6	NA	Hazard class 6.1; UN Number 1143
Crystalline silica, quartz	14808-60-7	1	100	ND	ND		Inorganic solid, N/A	This is a naturally occurring mineral that is not expected to biodegrade and it is not expected to bioaccumulate	NA	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Decamethyl cyclopentasiloxane	541-02-6	2	0.001	8.70E-06	>5000			Is not readily biodegradable in water, 0.14% biodegradation was reached after 28 days. Volatilisation from water surfaces is an important fate and transport process due to the Henry's Law Constant (3.3 x 10^6 Pa m^3/mol at 24.6°C). Estimated half lives for a model river and model lake are 5 hours and 6.8 days, respectively. Adsorption to suspended solids and sediment in the water column is expected to attenuate volatilisation from water surfaces. Calculated BCF of 1040-4920 L/kg indicate that it has a high to moderate potential to bioaccumulate in fish.	NA	No
Diammonium peroxidisulphate	7727-54-0	1	10	2.95	700		Inorganic, N/A	Is not expected to bioaccumulate. All decomposition products are ubiquitous in the environment	NA	Class 6.1; UN1444
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	2	0.1	ND	226			Readily biodegradable, 75% biodegradation reached after 28 days. Unlikely to bioaccumulate based on a low log K_{ow} value of 2.39	NA	No
Diethanolamine	111-42-2	1	65	ND	1600			Readily biodegradable, 93% degradation after 28 days. It is not expected to bioaccumulate based on an estimated BCF value of 2.3 obtained from OASIS Catalogic v.5.11.15 [BCF-base-line model v. 0208].	NA	No
Diethylene glycol	111-46-6	1	14	5.08	16500			Readily biodegradable, up to 92% degradation after 28 days. It is not expected to bioaccumulate based on a BCF value of 100 and a log K_{ow} value of -1.98.	NA	No
Dimethyl siloxanes and silicones	63148-62-9	1	0.001	695	>4800			It is considered not readily biodegradable under field conditions, the half-life in soil was 2.4 to 3.9 years. In freshwater sediments, 5 to 10% was hydrolysed after 1 year. Bioaccumulation is not expected due to its molecular weight.	Low concern polymer	No
Disodium octaborate tetrahydrate	12008-41-2	1	25	>2.03	2550		Inorganic, N/A	Inorganic mineral that is unlikely to bioaccumulate	NA	No
Distillates (petroleum), solvent-dewaxed heavy paraffinic	64742-65-0	1	1.40	2.18	>5000			Inherently biodegradable, with a reported mean degradation value of 31.13% after 28 days. There is some potential for bioaccumulation based on the log K_{ow} values (ranging from 1.99-18.02). However, the inherent biodegradability of this substance suggests that the bioaccumulation would be mitigated.	NA	No
Diutan	595585-15-2	1	0.1	ND	5000			Readily biodegradable, 95% degradation reached after 28 days. Is not expected to bioaccumulated based on a log K_{ow} of -3.56.	NA	No
Dodecamethylcyclohexasiloxane	540-97-6	2	0.001	ND	>2000			Is not readily biodegradable in water, 4.47% biodegradation reached after 28 days. Moderate potential to bioaccumulate based on BCF values of 240-1160 L/kg in fish.	NA	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Ethanol	64-17-5	1	1	124.7	>2000			Readily biodegradable, 84% degradation after 20 days. It is not expected to bioaccumulate based on a log K_{ow} value of -0.35	NA	Class 3; Packing Group II; UN Number 1170
Ethoxylated branched C13 alcohol	78330-21-9	1	10	ND	1700			Readily biodegradable, 75% degradation after 28 days. It is not expected to bioaccumulate based on an calculated log K_{ow} value of 4.9.	NA	No
Ethoxylated oleic acid	9004-96-0	1	0.438	1.6	>5050			Readily biodegradable, 83% degradation reached within 28 days after acidification. It is not expected to bioaccumulate based on a reported BCF value of 237 L/kg.	NA	No
Ethylene glycol	107-21-1	1	166	>2.5	7712			Readily biodegradable, 96% degradation after 28 days. Is not expected to bioaccumulated based on a calculated log K_{ow} values of -1.36 and a BCF value of 10 for fish	NA	No
Fatty acids, C8-C16, ethylhexyl ester	135800-37-2	1	6.31	>5.7	>2000			Readily biodegradable, 97% degradation after 30 days. Bioaccumulation is not expected	NA	No
Fatty acids, tall-oil, ethoxylated	61791-00-2	1	1	ND	>10000			It is considered readily biodegradable based on experimental results for a surrogate chemical which resulted in 90-100% degradation after 28 days. It is not considered to be bioaccumulative based on low BCF values.	NA	No
Gelatins	9000-70-8	1	0.227	ND	ND			A natural polymer that is readily biodegradable. Low potential to bioaccumulate	Chemical identified as low concern to human health	No
Glutaraldehyde	111-30-8	2	1.00	0.8	123			Readily biodegradable, 90-100% biodegradation reached after 28 days. It is not expected to bioaccumulate based on a measured log K_{ow} value of -0.26 @ pH 7	NA	Class 8; Packing Group III; UN3265 (Corrosive Liquid, Acidic, Organic, N.O.S. (Contains Glutaraldehyde))
Glycerine	56-81-5	1	0.433	ND	>5000			Readily biodegradable, 92% degradation after 30 days. It is not expected to bioaccumulate based on an experimental log K_{ow} of -1.75	Chemical identified as low concern to human health by application of expert validated rules	No
Guar gum	9000-30-0	1	667	ND	7060			It is expected to readily undergo microbial biodegradation. This polymer has a low potential to bioaccumulate	Chemical identified as low concern to human health	No
Hydrochloric acid	7647-01-0	1	474	5666	238		Dissociates completely	Dissolves completely in water. Dissociates completely to hydrogen (H^+) and chloride (Cl^-). Both ions are ubiquitous in the environment	NA	Class 9; Packing Group II or III; UN1789
Hydrotreated light petroleum distillate	64742-47-8	2	3.15	4.951	>5000			It is expected to be readily biodegradable, 69% degradation after 28 days. It is expected to have constituents with the potential to bioaccumulate	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Hydroxylpropyl guar	39421-75-5	1	1.35	ND	7060			It is expected to be biodegradable. It is not expected to bioaccumulate based on its high molecular weight	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	No
Iron gluconate	299-29-6	1	2.50	ND	2237			Readily biodegradable, 78% after 28 days. It has a low potential to bioaccumulate based on an estimated BCF value of 3.162 L/kg obtained from EPISUITE.	NA	No
Magnesium Silicate Hydrate (talc)	14807-96-6	1	0.1	2.1	>5000		Inorganic, N/A	Biodegradability is not relevant thus it meets the screening criteria for persistence. Bioaccumulation not expected to occur based on its log K_{ow} value of -9.4.	Chemical identified as low concern for human health	No
Methanol	67-56-1	1	4	87.5	6200			Is readily biodegradable in sea water (84 and 95% after 10 and 20 days, respectively) and soil (53.4% degradation under aerobic conditions and 46.3% degradation under anaerobic conditions). It has a BCF of 1.0 in fish which suggests that it has a low potential to bioaccumulate	NA	Class 8; Packing Group III; UN3265
Non-crystalline Silica (impurity)	7631-86-9	1	0.1	ND	ND		Inorganic, N/A	This is a naturally occurring mineral that is not expected to biodegrade and it is not expected to bioaccumulate	NA	No
Octamethylcyclotetrasiloxane	556-67-2	2	0.001	3.60E-05	>4800			Is not biodegradable in water. 3.7% biodegradation reached after 29 days. Susceptible to biodegradation in soil. High potential to bioconcentrate in fish with a BCF value of 12400 L/kg after 28 days. Identified as a PBT substance by the European Union.	NA	No
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy	31726-34-8	1	10	3.9	614			It is considered to be readily biodegradable, reaching 90.4% degradation after 28 days. It is not expected to bioaccumulate based on an experimental log K_{ow} value of 0.81.	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	No
Polyethylene glycol	25322-68-3	1	16	ND	25700			No data available specific to this chemical. Data on some of the major constituents indicate that the low molecular weight polyethylene glycols are inherently biodegradable, have a low potential for bioaccumulation.	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	No
Polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate	136793-29-8	1	0.1	ND	>5000			No data is available. Not expected to be readily biodegradable or bioaccumulate due its molecular weight and low water solubility (1000 g/L). Less than 10% biodegradation after 44 days.	NA	No
Polypropylene glycol	25322-69-4	1	0.353	ND	500			Readily biodegradable, 86.7% degradation after 28 days. It is not expected to bioaccumulate based on log K_{ow} values of <0.3 and 0.9.	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	No

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Potassium chloride	7447-40-7	1	8.27	ND	3020		Dissociates completely	Dissociates completely in aqueous media. Will dissociate to potassium and chloride ions which are not expected to bioaccumulate.	Chemical identified as low concern to human health by application of expert validated rules	No
Propan-2-ol	67-63-0	1	0.1	19000	4700			It is readily biodegradable, 49% biodegradable after 5 days. Not expected to bioaccumulate based on a log K_{ow} value of 0.05	NA	Class 3; Packing Group II; UN1219
Propylene glycol n-propyl ether	1569-01-3	1	1.03	1725	>2000			Readily biodegradable, 91.5% degradation after 28 days. It is not expected to bioaccumulate based on a log K_{ow} of 0.621	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis of the Tier 1 IMAP Assessment.	Class 3; Packing Group III; UN1993
Silica dioxide	112926-00-8	1	0.003	>0.69	>5000		Inorganic, N/A	A naturally-occurring material not expected to degrade.	Chemical identified as low concern to human health by application of expert validated rules	No
Siloxanes and silicones, dimethyl, reaction products with silica	67762-90-7	1	0.001	0.695	>4800			It is not readily biodegradable with a half life in soil of 2.4-3.9 years. In freshwater sediments it is hydrolysed after 1 year. It is not expected to bioaccumulate	Low concern polymer	No
Sodium bicarbonate	144-55-8	1	1.93	>4.74	>4000		Dissociates completely	Dissociates completely to sodium (Na^+) and bicarbonate (HCO_3^-) ions which are both ubiquitous in the environment. It will not adsorb on particulate matter or surfaces and will not accumulate	Chemical identified as low concern to human health by application of expert validated rules	No
Sodium bisulfite	7631-90-5	1	47	>5.5	1540		Dissociates completely	Dissociates in water to form (Na^+) ions, bisulfite ions (HSO_3^-), sulfite (SO_2^{3-}) ions, and sulfur dioxide (SO_2) which is a gas. It is not expected to bioaccumulate in the environment because of its dissociation to ionic species and a gas.	NA	No
Sodium carbonate	497-19-8	1	0.002	2.3	2800		Dissociates completely	Dissociates completely to sodium (Na^+) and carbonate (CO_3^{2-}) ions which are both ubiquitous in the environment. It is not expected to bioaccumulate.	NA	No
Sodium Chloride	7647-14-5	1	1	>42	>3550		Dissociates completely	Dissociates completely in aqueous solutions to sodium and chloride which are ubiquitous in the environment. Therefore, this chemical is not expected to bioaccumulate.	Chemical identified as low concern to human health by application of expert validated rules	No
Sodium diacetate	126-96-5	1	13	ND	5600			Readily biodegradable, 99% degradation after 28 days. It is not expected to bioaccumulate based on a log K_{ow} of -3.72	Chemical identified as low concern to human health by application of expert validated rules	No
Sodium hydroxide	1310-73-2	1	126	ND	325		Dissociates completely	Dissociates completely in the aquatic environment to ubiquitous ions (sodium and hydroxyl). It is not expected to bioaccumulate	NA	Class 8; Packing Group II; UN1824, Corrosive liquid

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Sodium iodide	7681-82-5	1	1	ND	3118		Inorganic, N/A	Dissociates in water to (Na^+) and (I^-) ions. It is not bioaccumulative	Chemical not considered to pose an unreasonable risk to health of workers and public health on the basis for the Tier 1 IMAP Assessment.	Hazard class 9; UN3077
Sodium perborate tetrahydrate	10486-00-7	1	1.02	1.17	2567		Inorganic, N/A	Unlikely to bioaccumulate	NA	No
Sodium persulfate	7775-27-1	1	25	>5.1	895		Dissociates completely	Dissociates in aqueous media to the sodium cation and persulfate anion. The persulfate anion will readily hydrolise (decompose) to sulfate ions.	NA	Clas 5.1; Packing Group: III; UN1505
Sodium polyacrylate	9003-04-7	1	0.325	ND	>5000			It is not readily biodegradable. It is not expected to bioaccumulate due to its high molecular weight	Polymer identified as low concern to human health by application of expert validated rules	No
Sodium sulfate	7757-82-6	1	0.1	>2.4	>2000		Dissociates completely	Dissociates in aqueous media to sodium and sulfate ions, which are ubiquitous in the environment. It is not expected to bioaccumulate.	Chemical identified as low concern to human health by application of expert validated rules	No
Sodium Sulfite	7757-83-7	1	0.00427	>5.5	2610		Dissociates completely	Dissociates in water to form sodium (Na^+) ions, sulphite (SO_2^{3-}) ions, and bisulphite ions (HSO_3^-).It is not expected to bioaccumulate in the environment because of its dissociation to ionic species and a gas.	NA	No
Sodium Tetraborate Decahydrate	1303-96-4	1	1	>2.01	>2500		Inorganic, N/A	It is unlikely to bioaccumulate due to its high water solubility.	NA	No
Sodium thiosulfate	7772-98-7	1	0.937	>2500	>2000		Dissociates completely	Dissociates in aqueous media to sodium (Na^+) and thiosulfate ($S_2O_3^{2-}$) ions which are ubiquitous in the environment. It is not expected to bioaccumulate.	Chemical identified as low concern for human health	No
Sorbitan monooleate polyoxyethylene derivative	9005-65-6	1	13	ND	>30			Readily biodegradable, 61% degradation after 28 days. It has a low potential for bioaccumulation	NA	No
Sorbitan, mono-9-octadecenoate, (Z)	1338-43-8	1	13	>5	>15900			Inherently biodegradable. It has a low potential for bioaccumulation.	NA	No
Tetrasodium ethylenediaminetetraacetate	64-02-8	1	0.001	ND	1700			It is not readily biodegradable; however, it can degrade under realistic environmental surface water conditions. Therefore, considered ultimately biodegradable. It is resistant to hydrolysis. It has a low potential to bioaccumulate based on BCF values of 1.8 and 1.1 from a 28 day fish test.	NA	No
Tributyl tetradecyl phosphonium chloride	81741-28-8	2	28	<0.05	>10002			It is not readily biodegradable in an OECD 301 test; however, after 24 and 168 hours, degradation was >81% and >98% in a die-away (stimulation) test and in activated sludge, there was >40% degradation after 30 days. It is not expected to bioaccumulate based on a reported log Kow of 2.45.	NA	Class 8 and 6.1; Packing Group II; UN2922

Chemical Name	CAS Number	Tier	Concentration in Injected Fluid (mg/L)	LC_{50} (mg/L)	Rat Lethal Dose (mg/kg)	Ratio of Lethal Dose to Maximum Concentration	Persistence	Environmental Fate Summary	NICNAS - Low Concern Chemical/Polymer	Dangerous Goods Code Required for Transport
Triethanol amine	102-71-6	1	0.469	ND	6400			Readily biodegradable, 96% degradation after 19 days. It has a low potential to bioaccumulate based on reported BCF values <0.4 and <3.9 at concentrations of 2.5 mg/L and 0.25 mg/L.	NA	No
Ulexite	1319-33-1	1	209	ND	ND		Inorganic, N/A	It is not expected to bioaccumulate based on BCF values of <0.1 to 10.5 in fish and oysters	NA	No
Urea	57-13-6	1	0.1	ND	1500			It is readily biodegradable, reaching 90-100% degradation after 21 days. It has a low potential to bioaccumulate with BCF values in fish reported as 1 or <10.	Chemical identified as low concern to human health by application of expert validated rules	No
Vinylidene chloride/methylacrylate copolymer	25038-72-6	1	0.1	ND	ND		No Data	This polymer is not expected to undergo rapid degradation. However, bioaccumulation is expected to be minimal based on its molecular weight (>1000 g/mol)	Low concern polymer	No

Ratio of Lethal Dose to Maximum Concentration Key	
	No Data
	≥ 100
	10 to 100
	1 to 10
	≤ 1

	Moderate but uncertain. Predicted risk or similar chemical tested.
	High but uncertain. Predicted risk or similar chemical tested.
	Very High but uncertain. Predicted risk or similar chemical tested.
ND	No data
Inorganic, N/A	Chemical is inorganic,.biodegradation assessment N/A not applicable.

Notes:
% = percent; BCF = bioconcentration factor; g/L = grams per litre; g/mol = grams per mol; Kow = octanol water coefficient; LC = lethal concentration; L/kg = litres per kilogram; mg/L = milligrams per litre; mg/kg = milligrams per kilogram; QSAR = Quantitative Structure Activity Relationship

Refer to **Appendix C** for additional information on chemical.

Persistence Legend	
Colour/symbol	**Risk Level**
	Very Low
	Low
	Moderate
	High
	Very High
	Low but uncertain. Predicted risk or similar chemical tested.

2.3 Tier 2 Assessment

Of the chemicals evaluated for the three hydraulic fracturing system formulations, the following additives were carried through to Tier 2 assessment:

- Hydrotreated light petroleum distillate (CAS number 64742-47-8) based on the potential for inhalation exposures to workers during hydraulic fracturing activities.
- Chemicals identified in the Tier 1 assessment with a high ecotoxicity hazard assessment and therefore having a potential avian wildlife exposure to fluids stored in treatment tanks; meeting this criterion and having the requisite toxicity data for a Tier 2 assessment include:
  - Amine oxides, cocoalkyldimethyl (CAS number 61788-90-7)
  - Chlorous acid, sodium salt (CAS number 7758-19-2)
  - Crontonaldehyde (CAS number 123-73-9)
  - Glutaraldehyde (CAS number 111-30-8)
  - Tributyl tetradecyl phosphonium chloride (CAS number 81741-28-8)
  - Dicoco dimethyl quaternary ammonium chloride (CAS number 61789-77-3)
  - Octamethylcyclotetrasiloxane (CAS number 556-67-2)
  - Decamethylcylopentasiloxane (CAS number 541-02-6)
  - Dodecamethylcyclohexasiloxane (CAS number 540-97-6)
  - Copper (II) sulfate (CAS number 7758-98-7)

2.3.1 Worker

Potential exposure to hydrotreated light petroleum distillate (CAS number 64742-47-8) was conducted for an occupational worker receptor for each hydraulic fracturing system formulation. **Appendix E** presents the Tier 2 assessment for this chemical.

A quantitative risk characterisation, or the Margin of Exposure approach (MoE), was used to assess the potential for health risk to workers from potential exposure to hydrotreated light petroleum distillate (NICNAS, 2017a and DoEE 2017). For each occupational activity scenario (i.e., transport, storage, mixing/blending drilling of hydraulic fracturing chemicals, injection of stimulation fluids, cleaning, maintenance and storage of flowback), an MoE was calculated from all routes of exposure using the following equation:

$$MoE = PoD/human\ dose$$

Where MoE = Margin of Exposure; PoD = Point of Departure for long-term health effects (e.g., No Observed Adverse Effect Level [NOAEL]) in mg/kg body weight [bw]/day); Human dose = measured or estimated human dose in mg/kg bw/day.

The potential for adverse effects decreases as the MoE increases. According to the guidance, an MoE is of low concern for human health if it is 100 or greater. The MoEs calculated were greater than this threshold (**Appendix E**). Therefore, the chemical is considered of low health concern for workers (refer to individual risk assessment dossiers [**Appendix C**] and **Table 2**). No further management controls are therefore considered necessary.

2.3.2 Avian Wildlife

Potential exposure to selected chemical additives and/or flowback in treatment tanks by avian wildlife was assessed for representative avian species. **Appendix F** presents the outcomes of the Tier 2 assessment for these chemicals.

The selected chemicals include:

- Amine oxides, cocoalkyldimethyl (CAS number 61788-90-7)
- Chlorous acid, sodium salt (CAS number 7758-19-2)
- Crontonaldehyde (CAS number 123-73-9)
- Glutaraldehyde (CAS number 111-30-8)
- Tributyl tetradecyl phosphonium chloride (CAS number 81741-28-8)
- Dicoco dimethyl quaternary ammonium chloride (CAS number 61789-77-3)
- Octamethylcyclotetrasiloxane (CAS number 556-67-2)
- Decamethylcylopentasiloxane (CAS number 541-02-6)
- Dodecamethylcyclohexasiloxane (CAS number 540-97-6)
- Copper (II) sulfate (CAS number 7758-98-7)

The potential exposure pathway for avian wildlife was assessed based on the potential ingestion of waters containing the selected chemicals (including flowback) from treatment tanks that were used for storage during the hydraulic fracturing activities of approximately three weeks. If a chemical was included in multiple fluid systems (e.g., glutaraldehyde), the maximum injected concentration (present in any of the fluid systems) was used in the Tier 2 assessment. Potential dietary intake of water containing these chemicals was compared to toxicity reference values developed specifically for avian wildlife to estimate a hazard quotient; a potential hazard quotient threshold level less than 1 indicates there are no unacceptable exposures to the avian species.

The hazard quotient for all the assessed avian species was orders of magnitude less than the threshold hazard quotient level of 1 (**Appendix F**). Therefore, there were no unacceptable exposures to the avian species. In addition, as a further conservative consideration, even if the potential exposure period is expanded to one year, the hazard quotient for the assessed avian species still will be orders of magnitude less than the threshold hazard quotient level of 1.

3 Summary and Risk Management

The goal of the chemical risk assessment was to demonstrate that potential risks associated with hydraulic stimulation chemicals proposed for use by Imperial and Imperial A across their NT tenement have been eliminated or reduced as much as is reasonably practicable to potentially exposed human and ecological receptors.

The life cycle of the hydraulic stimulation fluid system chemicals was assessed specifically for hydraulic stimulation operations and included:

- Activities associated with hydraulic stimulation chemical mixing and use at the well pad, and
- Management of flowback water (i.e., stored on-site) during or after the completion of hydraulic stimulation activities at the well pad.

The hydraulic stimulation chemicals within the life cycle (i.e., mixing, usage and storage) may result in potential exposure to human receptors and the environment through accidental releases. These potential releases, whilst unexpected, are considered to have a very low probability of occurrence and are constrained by the EMP requirements to managing risk, existing legislative requirements and the ongoing mitigating of potential impacts.

inGauge has developed and implemented a range of systems and plans to control the transportation and storage of chemicals during field development and operational activities. This includes personnel induction and training, effective traffic management and routing to minimise the potential for accidents and spill management planning and response equipment. These systems and processes are considered effective in lowering the probability of occurrence of consequence associated with transportation incidents.

The human health and ecological hazard mitigation information provided in the chemical risk assessment dossiers and SDSs primarily focuses on safe handling, transportation and worker protection.

Based on the outcomes of this assessment, no further management controls are considered necessary.

4 Limitations

EHS Support Pty Ltd ("EHS Support") has prepared this report in accordance with the usual care and thoroughness of the consulting profession for the use of inGauge and only those third parties who have been authorised in writing by EHS to rely on the report. It is based on generally accepted practices and standards at the time it was prepared. No other warranty, expressed or implied, is made as to the professional advice included in this report. It is prepared in accordance with the scope of work and for the purpose outlined in the Proposal email dated 30 November 2021 and subsequent emails.

The methodology adopted and sources of information used by EHS Support are outlined in this report. EHS Support has made no independent verification of this information beyond the agreed scope of works, and EHS Support assumes no responsibility for any inaccuracies or omissions. No indications were found during our investigations that the information contained in this report as provided to EHS Support was false.

This report was prepared through December 2021 and November 2023 and is based on the information reviewed at the time of preparation. EHS Support disclaims responsibility for any changes that may have occurred after this time.

This report should be read in full. No responsibility is accepted for the use of any part of this report in any other context or for any other purpose, or by third parties. This report does not purport to give legal advice. Legal advice can only be given by qualified legal practitioners.

5 References

Australian Governments: Geological and Bioregional Assessment for the Beetaloo GBA (https://www.bioregionalassessments.gov.au/assessments/geological-and-bioregional-assessment-program/beetaloo-sub-basin/beetaloo-gba-region-stage-two-report)

Australian Industrial Chemicals Introduction Scheme. 2022. Chemical Information Database. Available online at: https://www.industrialchemicals.gov.au/chemical-information/search-assessments

Department of the Environment and Energy (DoEE). 2017. Exposure Draft - Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

enHealth. 2012. Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards.

inGauge Energy Australia (inGauge). 2020. Environment Management Plan Imperial Oil and Gas 2020 Hydraulic Fracturing Program NT Exploration Permit (EP) 187.

inGauge Energy Australia (inGauge). 2021. Environment Management Plan Imperial Oil and Gas 2021-2025 EP187 Work Program NT Exploration Permit (EP) 187.

inGauge Energy Australia (inGauge). 2023. Environment Management Plan Imperial Oil and Gas 2021-2025 EP187 Work Program NT Exploration Permit (EP) 187.

NEPC. 2013. National Environment Protection (Assessment of Site Contamination) Measure 1999 (ASC NEPM); Schedule B4, Site-specific health risk assessment methodology. Amended 2013.

NEPC. 2009. Environmental risk assessment guidance manual for industrial chemicals. February. Available online at: https://www.nepc.gov.au/sites/default/files/2022-09/cmgt-nchem-eragm-industrial-chemicals-200902.pdf

National Industrial Chemicals Notification and Assessment Scheme (NICNAS). 2017a. National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Overview. Department of the Environment and Energy. Department of Health. National Industrial Chemicals Notification and Assessment Scheme.

NICNAS. 2017b. Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NT. 2018. Scientific Inquiry into Hydraulic Fracturing of Onshore Unconventional Reservoirs in the Northern Territory. Final Report. April. Darwin Northern Territory.

NT. 2019. Draft Guideline for the Preparation of an Environmental Management Plan under the Petroleum (Environment) Regulations.

NT. 2023. Petroleum (Environment) Regulations 2016. As in force at 22 June 2023.

Northern Territory Governments POINT online mapping and data catalogue
(https://point.nt.gov.au/weave/point.html)

Tables

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione	9051-89-2	2.1804	**PNECwater** - not derived **PNECsoil** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low Concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Not considered persistent. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	2-Ethyl hexanol	104-76-7	0.07	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Fathead minnow - 28.2 mg/L -96-hr LC_{50} Golden Orfe - 17.1 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 39 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Scenedesmus subspicatus* - 11.5 mg/L (biomass); 16.6 mg/L (growth rate) -EC_{10} *Scenedesmus subspicatus* - 3.2 mg/L (biomass); 5.3 mg/L (growth rate) Chronic Aquatic - Algae and other aquatic plants -72-hr EC_{10} *Scenedesmus subspicatus* was 3.2 mg/L (biomass) and 5.3 mg/L (growth rate) **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.012 mg/L (Acute Daphnia) **$PNEC_{soil}$** - 0.027 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is 2.9 No bioconcentration studies PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Acetaldehyde	75-07-0	0.07	**Aquatic Toxicity** Acute Aquatic-Fish -96-hr LC_{50} - *Pimephales promelas* - 30.8 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 48.3 mg/L Acute Aquatic - Algae and other aquatic plants -120d EC_{50} - *Nitzscheria linearis* >237 and <249 mg/L **Chronic Aquatic** -No experimental studies are available. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** - 0.3 mg/L (acute fish) **$PNEC_{soil}$** - 0.012 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Eye/respiratory irritant; animal carcinogen (inhalation); suspect mutagen. Ecological Hazard - Harmful to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Hazard Assessment: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow is -0.17 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione	9051-89-2	Tier 1	PBT Assessment: The overall conclusion is that 1,4-Dioxane-2,5-dione, 3,6-dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione and (3S,6S)-3,6-dimethyl-1,4-dioxane-2,5-dione is not a PBT substance Management: No additional management required, Tier 1 screening satisfied.	NA
	2-Ethyl hexanol	104-76-7	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that 2-ethylhexanol is not a PBT substance. Qualitative assessment indicates that this chemical is of low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Acetaldehyde	75-07-0	Tier 1 (Qualitative/ PBT Exposure Assessment)	PBT Assessment: The overall conclusion is that acetaldehyde is not a PBT substance. Qualitative assessment indicates that this chemical may pose a hazard to human health (e.g., eye/respiratory irritant). The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Acetic acid	64-19-7	66.0	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - (test substance potassium acetate) >300.82 mg/L (as acetate ion) -96-hr LC_{50} *Danio rerio* - (test substance potassium acetate) >300.82 mg/L (as acetate ion) -96-hr LC_{50} *Oncorhynchus mykiss* - (test substance acetic acid) 64.8 mg/L (measured) -96-hr LC_{50} *Oncorhynchus mykiss* - (test substance acetic acid) 31.3 mg/L - 67.6 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - (test substance potassium acetate) >300.82 mg/L (as acetate ion) -48-hr EC_{50} *Daphnia magna* - (test substance acetic acid) 79.5 mg/L (measured) -48-hr EC_{50} *Daphnia magna* - (test substance acetic acid) 18.9 mg/L (measured) Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Desmodesmus subspicatus* - 486.5 mg/L Chronic Aquatic - Fish -21-day *Oncorhynchus mykiss* study - measured NOEC 57.2 mg/L (60% acetic acid) and 34.3 mg/L (100% acetic acid) Chronic Aquatic - Invertebrate -21-day *Daphnia magna* reproduction study measured NOEC 80 mg/L (60% acetic acid) and 31.4 mg/L (100% acetic acid) -21-day *Daphnia magna* reproduction study measured NOEC 22.7 mg/L (100% acetic acid) **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 3.0 mg/L (E(L)C50 test fish or *Dapnhia magna*) **$PNEC_{soil}$** - 0.04 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Corrosive, respiratory irritant Ecological Hazard - Low Concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Hazard Assessment: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Low Kow is -0.17 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Acrylamide acrylate copolymer	9003-06-9	22.0	**$PNEC_{water}$** - 0.1 mg/L (acute fish) **$PNEC_{soil}$** - not calculated	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low Concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Not biodegradable PBT Assessment: Does meet the criteria for persistence.	Environmental Fate Property: Not expected to bioaccumulate because of poor water solubility and high molecular weight PBT Assessment: Does not meet criteria for bioaccumulation
	Acrylamide, sodium acrylate polymer	25987-30-8	143	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. Due to poor solubility and high molecular weight not expected to be bioavailable. Does not contain any reactive functional groups. **PNECs** - not calculated	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low Concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Not biodegradable PBT Assessment: Does meet the criteria for persistence.	Environmental Fate Property: Not expected to bioaccumulate because of poor water solubility and high molecular weight PBT Assessment: Does not meet criteria for bioaccumulation

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Acetic acid	64-19-7	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -unlikely to cause harm to environment PBT Assessment: The overall conclusion is that acetic acid is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Acrylamide acrylate copolymer	9003-06-9	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS Assessment (2018) NICNAS assessed in an IMAP Tier 1 assessment and considers it a "polymer identified as low concern to human health by application of expert validated rules" PBT Assessment: The overall conclusion is that acrylamide/sodium acrylate copolymer is not a PBT substance. The estimated injected concentration did exceed the PNECs for this chemical and is not biodegradable. However, this chemical does not bioaccumulate and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Acrylamide, sodium acrylate polymer	25987-30-8	Tier 1 (NICNAS/ PBT)	NICNAS Assessment (2018) NICNAS assessed in an IMAP Tier 1 assessment and considers it a "polymer identified as low concern to human health by application of expert validated rules". PBT Assessment: The overall conclusion is that acrylamide/sodium acrylate copolymer is not a PBT substance. Management: No additional management required, Tier 1 screening satisfied.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Acrylonitrile	107-13-1	0.10	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Oryzias latipes - 5.1 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 2.5 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - 10 mg/L (biomass) Chronic Aquatic - Algae and other aquatic plants -30-day LOEC Pimephales promelas in a fish early life stage test was 0.34 mg/L. A NOEC of 0.17 mg/L is derived by LOEC/2. -The 21-day NOEC from a Daphnia reproduction test is 0.5 mg/L (ECHA) [Kl. score = 1]. -The 72-hr NOEC to Pseudokirchneriella subcapitata is 0.95 mg/l based on growth rate (ECHA) [Kl. score = 1]. **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.017 mg/L **$PNEC_{soil}$** - 0.002 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - High acute toxicity (oral, dermal, inhalation); skin/respiratory irritant; skin sensitizer; animal carcinogen (oral and inhalation) Ecological Hazard - Toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Inherently biodegradable PBT Assessment: Does not meet the criteria for persistence.	Environmental Fate Property: log Kow 1.04 PBT Assessment: Does not meet criteria for bioaccumulation
	Alcohols, C10-16, ethoxylated propoxylated	69227-22-1	71	**Aquatic Toxicity** -Freshwater fish: 2 species, 720 to 1,500 µg/L. -Freshwater crustaceans: 2 species, 590 to 860 µg/L. -Freshwater rotifers: 1 species, Brachionus calyciflorus, 1,300 µg/L -Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L. **Terrestrial Toxicity** -No studies are available **$PNEC_{water}$** - 0.14 mg/L (ANZECC Water Quality Guideline for alcohol ethoxyates) **$PNEC_{soil}$ -** 0.3 - 10.7 mg/kg dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow range from <5 to 387.5 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Alcohols, C12-15, ethoxylated	68131-39-5	1.0	**Aquatic Toxicity** Toxicity values (NOECs) utilised in development of ANZECC water quality guideline for alcohol ethoxylates: -Freshwater fish: 2 species, 720 to 1,500 µg/L -Freshwater crustaceans: 2 species, 590 to 860 µg/L. -Freshwater rotifers: 1 species, Brachionus calyciflorus, 1,300 µg/L -Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L. - Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330µg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320, and 1,520 µg/L. **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.140 mg/L (ANZECC Water Quality Guideline for alcohol ethoxyates) **$PNEC_{soil}$** - 0.9 - 5.6 (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow range from <5 to 387.5 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Alcohols, C12-16, ethoxylated	68551-12-2	1.0	**Aquatic Toxicity** Toxicity values (NOECs) utilised in development of ANZECC water quality guideline for alcohol ethoxylates: -Freshwater fish: 2 species, 720 to 1,500 µg/L -Freshwater crustaceans: 2 species, 590 to 860 µg/L. -Freshwater rotifers: 1 species, Brachionus calyciflorus, 1,300 µg/L -Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L. - Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330µg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320, and 1,520 µg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.140 mg/L (ANZECC Water Quality Guideline for alcohol ethoxyates) **$PNEC_{soil}$** - 0.0 to 10.7 mg/kg dry weight soil (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow range from <5 to 387.5 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Mar-20	Acrylonitrile	107-13-1	Tier 1 (PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that acrylonitrile is not a PBT substance. Qualitative Assessment indicated human health hazard of skin/respiratory irritant, acute toxicity via oral, dermal, and inhalation pathway; and, carcinogenic to animals. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA
	Alcohols, C10-16, ethoxylated propoxylated	69227-22-1	Tier 1 (PBT/Exposure Assessment)	PBT Assessment: The overall conclusion is that Alcohols, C10-16, ethoxylated propoxylated is not a PBT substance. Qualitative Assessment indicated low concern to human health. While the estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Alcohols, C12-15, ethoxylated	68131-39-5	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Alcohols, C12-15, ethoxylated is not a PBT substance. Qualitative Assessment indicated low concern to human health; however harmful effects to aquatic life. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Alcohols, C12-16, ethoxylated	68551-12-2	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Alcohols, C12-16, ethoxylated is not a PBT substance. Qualitative Assessment indicated low concern to human health; however harmful effects to aquatic life. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA

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Evaluation of Compiled List of Chemicals
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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Alcohols, C6-12, ethoxylated propoxylated	68937-66-6	199	**Aquatic Toxicity** Toxicity values (NOECs) utilised in development of ANZECC water quality guideline for alcohol ethoxylates: -Freshwater fish: 2 species, 720 to 1,500 µg/L -Freshwater crustaceans: 2 species, 590 to 860 µg/L. -Freshwater rotifers: 1 species, Brachionus calyciflorus, 1,300 µg/L -Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L. - Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330µg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320, and 1,520 µg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.140 mg/L **$PNEC_{soil}$** - 0.03 to 0.87 mg/kg dry weight soil	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow range from <5 to 387.5 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Aldol	107-89-1	1.29	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} - Fish - 134 mg/L -48-hr EC_{50} *Daphnid* - 840 mg/L -96-hr EC_{50} *Green Algae* - 692 mg/L **Chronic Aquatic** -No experimental studies are available. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** - 0.13 mg/L **$PNEC_{soil}$** - 0.002 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Expected to be eye/respiratory irritant; low concern for systemic toxicity. Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: low kow = -0.722 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-28-4	1.0	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} - Danio rerio - 5.1 mg/L -48-hr EC_{50} Daphnia magna - 3.2 mg/L -72-hr EC_{50} Desmodesmus subspicatus - 18.6 mg/L **Chronic Aquatic** -The 28-day NOEC to Oncorhynchus mykiss in a fish chronic toxicity study is 0.32 mg/L [nominal] and 0.26 mg/L [measured] (ECHA) [Kl. score =2]. -The 21-d NOEC in a Daphnia reproduction test is 0.1 mg/L [nominal] and 0.07 mg/L [measured] (ECHA) [Kl. score = 2]. -The 72-hr EC10 to Desmodesmus subspicatus is 1.4 mg/L (ECHA) [Kl. score = 2]. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** -0.007 mg/L (Acute *Daphnia*) **$PNEC_{soil}$** - 0.16 (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Skin/eye irritant Ecological Hazard - Toxic to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Inherently biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: > 6 (experimental) PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Amine oxides, cocoalkyldimethyl	61788-90-7	3.0	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} - Salmo gairdneri - 13 mg/L -96-hr LC_{50} - Brachydanio rerio - 1.0 mg/L -96-hr LC50 - Leuciscus idus melanotus - 4.3 mg/L -48-hr EC_{50} Daphnia magna - 2.9 mg/L -72-hr EC_{50} Selenastrum capricornutum - 0.29 mg/L **Chronic Aquatic** -No studies available **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** -0.009 mg/L (Acute *Algae*) **$PNEC_{soil}$** - 0.18 mg/kg dry weight soil (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Skin irritant/Severe eye irritant Ecological Hazard - Very toxic to aquatic life. Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: <2.7 PBT Assessment: Does not meet the criteria for bioaccumulation

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Alcohols, C6-12, ethoxylated propoxylated	68937-66-6	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Alcohols, C6-12, ethoxylated propoxylated is not a PBT substance. Qualitative Assessment indicated low concern to human health. While the estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Aldol	107-89-1	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that aldol is not a PBT substance. Qualitative assessment indicates that this chemical may pose a hazard to human health (e.g., eye/respiratory irritant). The estimated injected concentration did exceed the PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA
	Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-28-4	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Amides, tall-oil fatty, N,N-bis(hydroxyethyl) is not a PBT substance. Qualitative Assessment indicated human health hazard of skin/eye irritant. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA
	Amine oxides, cocoalkyldimethyl	61788-90-7	Tier 2	PBT Assessment: The overall conclusion is that Amine oxides, cocoalkyldimethyl is not a PBT substance. Qualitative Assessment indicated human health hazard of skin/eye irritant. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to amine oxides, cocoalkyldimethyl (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Benzaldehyde	100-52-7	2.0	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} -Fathead minnow - 12.4 mg/L -96-hr LC_{50} -Rainbow trout- 11.2 mg/L -96-hr LC_{50} - Goldfish - 13.8 mg/L -96-hr LC_{50} - Channel catfish- 5.39 mg/L -96-hr LC_{50} - Bluegill - 1.07 mg/L -24-hr EC_{50} Daphnia - 50 mg/L **Chronic Aquatic** -7-day NOEC to 1- day Pimephales promelas larvae was 0.12 mg/L (measured) based on growth rate and mortality (ECHA) [Kl. score = 2]. -8-day NOEC to Scenedesmus quadricauda is 34 mg/L (ECHA) [Kl. score = 4]. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** -0.002 mg/L (Acute *Algae*) **$PNEC_{soil}$ -** 0.0003 mg/kg dry weight soil (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: 1.4 PBT Assessment: Does not meet the criteria for bioaccumulation
	Bismuth Oxide	1304-76-3	0.09	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} -Brachydanio rerio - >137 [WAF] and >100 [WAF]* mg/L -48-hr EC_{50} -Daphnia magna - >137 [WAF] and >100 [WAF]* mg/L -72-hr EC_{50} Daphnia - >137 [WAF] and >100 [WAF]* mg/L *As bismuth. The value for bismuth oxide is 223 mg/L (the molecular weight is 266 g/mol). **Chronic Aquatic** -No experimental studies are available. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** -1.0 mg/L **$PNEC_{soil}$ -** Cannot be derived using the equilibrium partitioning method.	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment:Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: slightly soluble in water PBT Assessment: Does not meet the criteria for bioaccumulation
	Butyl alcohol	71-36-3	1.0	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} -Pimephelas promelas - 1,376 mg/L -48-hr EC_{50} -Daphnia magna - 1,328 mg/L -72-hr EC_{50} - Pseudokirchneriella subcapitata - 225 mg/L **Chronic Aquatic** -21-d NOEC from a Daphnia reproduction test is 4.1 mg/L (ECHA) [Kl. score = 2]. -96-hr EC10 to Pseudokirchneriella subcapitata is 134 mg/L (ECHA) [Kl. score = 1]. **Terrestrial Toxicity** -No experimental studies are available. **$PNEC_{water}$** -0.08 mg/L (Acute *Algae*) **$PNEC_{soil}$ -** 0.004 mg/kg soil dry weight.	Qualitative Assessment: Human Health Hazard -Skin irritant/Severe eye irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow = 1 PBT Assessment: Does not meet the criteria for bioaccumulation

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Benzaldehyde	100-52-7	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that benzaldehyde is not a PBT substance. Qualitative assessment indicates that this chemical is of low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity to aquatic organisms. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Bismuth Oxide	1304-76-3	Tier 1 (Qualitative/ PBT)	PBT Assessment: The overall conclusion is that bismuth oxide is not a PBT substance. Qualitative assessment indicates that this chemical is of low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Butyl alcohol	71-36-3	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that butyl alcohol is not a PBT substance. Qualitative Assessment indicated human health hazard of Skin irritant/Severe eye irritant. The estimated injected concentration did exceed the PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Crontonaldehyde	123-73-9	0.12	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 0.65 mg/L -96-hr LC_{50} *Pimephales promelas* - 0.84 mg/L -96-hr LC_{50} *Lepomis macrochirus* - 3 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 2 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - 0.597 mg/L -96-hr EC_{50} *Pseudokirchneriella subcapitata* - <0.881 mg/L Chronic Aquatic - Fish -21-day *Oryzias latipes* early stage life toxicity NOEC 0.0247 mg/L Chronic Aquatic - Algae and other aquatic plants -96-hr *Pseudokirchneriella subcapitata* study EC_{10} 0.385 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.0005 mg/L (lowest NOEC) **$PNEC_{soil}$** - 0.00007 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard: Very high acute toxicity (dermal, inhalation); moderate-to-high acute toxicity (oral); skin/respiratory irritant; severe eye irritant; repeated inhalation exposures may cause nasal lesions; suspect mutagen. Ecological Hazard: Very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Experimental log Kow is 0.6 PBT Assessment: Does not meet the criteria for bioaccumulation.
	Chlorous acid, sodium salt	7758-19-2	0.12	**PNECwater** -0.001 mg/L (Acute Algae) **PNECsoil** -not derived	Qualitative Assessment: Human Health Corrosive; moderate-to-high acute oral toxicity. Repeated exposures may cause blood effects Ecological Hazard - Very toxic to aquatic life. Harmful to aquatic life with long lasting effects. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	PBT Assessment: Does not meet the criteria for bioaccumulation (ionic species)
	Choline Chloride	67-48-1	1096	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oryzias latipes* - >100 mg/L (nominal and measured) -96-hr LC_{50} *Leuciscus idus* - >10,000 mg/L (78% solution of choline chloride) Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 349 mg/L (nominal and measured) -48-hr EC_{50} *Daphnia magna* - >500 mg/L (78% solution of choline chloride) Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - >1,000 (nominal and measured) Chronic Aquatic - Invertebrate -21-day *Daphnia magna* reproduction test NOEC 30.2 mg/L (nominal and measured) Chronic Aquatic - Algae and other aquatic plants -72-hr *Pseudokirchneriella subcapitata* study NOEC 30.2 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.3 mg/L **$PNEC_{soil}$** - 0.007 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Experimental log Kow is -3.77 PBT Assessment: Does not meet the criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Crontonaldehyde	123-73-9	Tier 2	PBT Assessment: The overall conclusion is that Crontonaldehyde is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., acute toxicity, severe eye irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore, a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to crontonaldehyde (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Chlorous acid, sodium salt	7758-19-2	Tier 2	PBT Assessment: The overall conclusion is that butyl alcohol is not a PBT substance. Qualitative Assessment indicated human health hazard of Skin irritant/Severe eye irritant. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore, a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to chlorous acid, sodium salt (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Choline Chloride	67-48-1	NA	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that choline chloride is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Cinnamaldehyde	104-55-2	14	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Brachydanio rerio* - 4.15 mg/L -96-hr LC_{50} *Poecilia reticulata* - >3.5 Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 3.21 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Desmodesmus subspicatus* - 31.6 mg/L -72-hr EC_{50} *Chlorella vulgaris* - 16.09 mg/L Chronic Aquatic - Fish -28-day LOEC *Oryzias latipes* 66.08 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.04 mg/L (Acute Fish) **$PNEC_{soil}$** - 0.02 mg/kg dry weight soil (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Skin/eye irritant; skin sensitizer Ecological Hazard - Toxic to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow is 2.107 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Citric acid	77-92-9	4.0	**Aquatic Toxicity** Acute Aquatic - Fish -48-hr LC50 Leuciscus idus melanotus (golden orfe) - 440 mg/L and 760 mg/L -96-hr LC50 Lepomis macrochirus (fathead minnow)- >100 mg/L Acute Aquatic - Invertebrate -24-hr EC50 Daphnia magna - 85 mg/L (un-neutralised test solution) 1,535 mg/L in neutralised solution Acute Aquatic - Algae and other aquatic plants -8-day EC_0 Scenedesmus quadricauda - 640 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.44 mg/L (Acute Daphnia) **$PNEC_{soil}$** - 0.002 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Eye irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: log Kow is -1.61 to -1.80 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Cocobetaine	61789-40-0	2.62	**Aquatic Toxicity** Acute Aquatic The lowest acute LC/EC50 values for fish, Daphnia, and algae are all in the range of 1.3 – 2 mg active substance/L **Chronic Aquatic** -72-hr NOEC Daphnia - 0.932 mg active substance/L -72-hr NOEC algae 3.55 active substance/L -72-hr EC50 algae - 9.86 mg active substance/L **Terrestrial Toxicity** Two studies (without analytical monitoring) of effects on earthworms and higher plants showed low toxicity (no data provided). Refer to toxicity profile for additional information **$PNEC_{water}$** - 0.0032 mg/L (chronic fish) **$PNEC_{soil}$** - 0.028 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Skin irritant; skin sensitizer Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: BCF between 3 and 71 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Cinnamaldehyde	104-55-2	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that cinnamaldehyde is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA
	Citric acid	77-92-9	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) Qualitative Assessment indicated potential hazard to human health (e.g., eye irritant). PBT Assessment: The overall conclusion is that citric acid is not a PBT substance. The estimated injected concentration did exceed the PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA
	Cocobetaine	61789-40-0	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that cocobetaine is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Crystalline silica, quartz	14808-60-7	25	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. **$PNEC_{water}$** - not derived **$PNEC_{soil}$ -** not derived	Qualitative Assessment: Human Hazard: Inhalation: silicosis and lung cancer in humans. Oral/dermal: low concern. Ecological Hazard: Low concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: water-insoluble mineral; not bioavailable PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Diethanolamine	111-42-2	65	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 460 mg/L -96-hr LC_{50} *Pimephales promelas* - 1,460 mg/L (geometric mean of 96-h LC_{50} values of fry, juvenile, and subadult fish. not neutralised) -96-hr LC_{50} *Pimephales promelas* - 1,664 mg/L -48-hr LC_{50} *Lepomis macrochiru* s - 1,850 mg/L -24-hr LC_{50} *Carassius auratus* - >5,000 mg/L (neutralised) 800 (non-neutralised) Acute Aquatic - Invertebrate -48-hr EC_{50} *Ceriodaphnia dubia* - 30.1 mg/L (24°C), 89.9 (20°C) -48-hr EC_{50} *Daphnia magna* - 55 mg/L -48-hr EC_{50} *Daphnia magna* - 171 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - 9.5 mg/L (growth rate; Test 1), 19 (growth rate; Test 2) -72-hr EC_{50} *Desmodesmus subspicatus* - 14.9 mg/L (growth rate), 6.2 (biomass) -72-hr EC_{50} *Desmodesmus subspicatus* - 107.3 mg/L (growth rate), 74.5 (biomass) -72-hr EC_{50} *Chlorella vulgaris* - 778 mg/L (growth rate) Chronic Aquatic - Invertebrate -EC_{10} *Daphnia magna* 1.05 mg/L -NOEC *Daphnia magna* 0.76 mg/L Chronic Aquatic - Algae and other aquatic plants -EC_{10} *Pseudokirchneriella subcapitata* - 1.4 mg/L (growth rate, Test 1), 1.1 (growth rate, Test 2) -EC_{10} *Desmodesmus subspicatus* - 2.4 mg/L (growth rate), 2.0 (biomass) -EC_{10} (non-neutralised) *Desmodesmus subspicatus* - 85.7 mg/L (growth rate), 41.3 (biomass) -7-d NOEC *Pseudokirchneriella subcapitata* - 10 mg/L **Terrestrial Toxicity** -35-day LC_{50} earthworm (*Eisenia Andrei, Eisenia fetida, or Lumbricus terrestris*) - 4,141 mg/kg (mortality) -63-day EC_{50} earthworm - 776 mg/kg (reproduction) -63-day EC_{25} earthworm - 171 mg/kg (reproduction) -28-day LC_{50} springtails (*Folsomia candida*) 8,301 mg/kg (reproduction) -28-day EC_{50} earthworm - 4,205 mg/kg (reproduction) -28-day EC_{25} earthworm - 2,102 mg/kg (reproduction) **$PNEC_{water}$** - 0.02 mg/L (Chronic algea) **$PNEC_{soil}$** - 0.027 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Skin irritant/Severe eye irritant. Repeated exposure may cause liver, kidney and blood toxicity Ecological Hazard - Harmful to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Estimated BCF 2.3 PBT Assessment: Does not meet the criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Crystalline silica, quartz	14808-60-7	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Crystalline silica, quartz is not a PBT substance. Qualitative Assessment indicated hazardous to human health by the inhalation pathway; not hazardous by the oral/dermal route. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore a Tier 2 Assessment is not warranted.	NA
	Diethanolamine	111-42-2	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that diethanolamine is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Diethylene glycol	111-46-6	14	**Aquatic Toxicity** Acute Aquatic - Fish -96-h LC_{50} *Pimephales promelas* - 75,200 mg/L -96-h LC_{50} *Oncorhynchus mykiss* - 66,000 Acute Aquatic - Invertebrate -24-h EC_{50} *Daphnia magna* ->10,000 mg/L -48-hr EC_{50} *Daphnia magna* - 65,980 mg/L -48-hr EC_{50} *Daphnia magna* - 62,630 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L (for ethylene glycol) Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L (for ethylene glycol) -21 day - *Daphnia magna* - > 15,000 mg/L (for triethylene glycol) Chronic Aquatic - Algae -8-day TGK to algae *Scenedesmus quadricauda* 2,700 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 27 mg/L **$PNEC_{soil}$** - 0.36 mg/kg dry weight soil	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow = -1.98 (calculated) PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Disodium octaborate tetrahydrate	12008-41-2	25	**Aquatic Toxicity:** Following utilised by ANZECC to develop water quality guideline for boron Chronic Aquatic - Fish 32-day LOEC *O mykiss* - 0.04 mg/L 32-day LOEC *O mykiss* - 27.6 mg/L Chronic Aquatic - Invertebrates - 21-day LC_{50} *Daphnia magna* 4.665 mg/L - 21-day LC_{50} *Daphnia magna* 54.2 mg/L - NOEC 6.0 mg/L (reproduction) Chronic Aquatic - Algae and other aquatic plants -14-day NOEC *Chlorella pyrenoidosa* 0.4 mg/L -NOEC *Chlorella vulgaris* 5.2 mg/L. **$PNEC_{water}$** - 0.37 mg/L (ANZECC water quality guideline for boron) **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard -Known or presumed human reproductive toxicant. Ecological Hazard - Moderate concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable.	Environmental Fate Property: Water soluble and not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Ethanol	64-17-5	1.0	**Aquatic Toxicity:** Acute Toxicity Algae (most sensitive) 96-hr EC_{50} for *Chlorella vulgaris* 1,000 mg/L Chronic Aquatic - Invertebrates - lowest NOEC *Cerodaphnia sp.* 9.6 mg/L Chronic Aquatic - Algae and other aquatic plants - 5-day NOEC *Skeletonema costatum* 3,240 to 5,400 mg/L (cell count) -5-day EC_{50} *Skeletonema costatum* 10,943 - 11,619 mg/L. **Terrestrial Toxicity:** Toxicity to Terrestrial Plants The 7-d NOEC values of higher (vascular) plants Lemna gibba and L. minor were 280 and 778 mg/L, respectively. The EC50 values for both plants were 4,432 mg/L (Cowgill, 1991). Toxicity to Terrestrial Organisms -48-hr LC_{50} oligochaete worm (*Eisenia foetida*) 0.1-1.0 mg/cm^2 (200-2000 mg/L). **$PNEC_{water}$** - 1.0 mg/L (chronic *Daphnia*) **$PNEC_{soil}$** - 0.013 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: BCF - estimated 3.16 L/kg PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Diethylene glycol	111-46-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Diethylene glycol is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Disodium octaborate tetrahydrate	12008-41-2	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Disodium octaborate tetrahydrate is not a PBT substance. Qualitative assessment indicated known or presumed human reproductive toxicant. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Ethanol	64-17-5	Tier 1 (NICNAS/ PBT)	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -Limited assessment - detailed information unavailable therefore, chemical assessed at earliest most conservative level of testing, which overestimates risk. Therefore, classified as potentially harmful at this level, but further information and testing wold be required to determine actual level of risk PBT Assessment: The overall conclusion is that ethanol is not a PBT substance. PBT assessment indicated criteria for persistence, bioaccumulation, and toxicity not met. Additionally, concentration injected did not exceed ecotoxicity and PNEC screening values and potential aquatic exposure pathway incomplete (refer to text). Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Ethoxylated branched C13 alcohol	78330-21-9	10	**Aquatic Toxicity** Freshwater fish: 2 species, 720 to 1,500 µg/L. Freshwater crustaceans: 2 species, 590 to 860 µg/L. Freshwater rotifers: 1 species, Brachionus calyciflorus, 1,300 µg/L Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 µg/L. Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 µg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320, and 1,520 µg/L. **Chronic Toxicity** -No studies available **Terrestrial Toxicity** -No studies are available **$PNEC_{water}$** - 0.14 mg/L **$PNEC_{sediment}$** - 0.71 mg/kg sediment wet weight **$PNEC_{soil}$** - 0.56 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Harmful to aquatic life with long lasting effects PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: 4.9 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Ethylene glycol	107-21-1	166	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimephales promelas* - >72,860 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 22,810 mg/L and 24,591 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - >100 mg/L, 46,300 mg/L (20°C), 51,000 mg/L (24°C) -48-hr EC50 *Ceriodaphnia dubia-affinis* - 25,800 mg/L (20°C), 10,000 mg/L (24°C) Acute Aquatic - Algae and other aquatic plants -96-hr IC_{50} *Selenastrum capricornutum* - 10,940 mg/L -96-hr NOEC *Selenastrum capricornutum* - 10,000 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L Chronic Aquatic - Algae -72-hr NOEC *Pseudokirchneriella subcapitata* - >100 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 10 mg/L **$PNEC_{soil}$** - 0.13 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Repeated exposures may cause kidney toxicity Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: -Calculated log Kow is -1.36 -BCF in golden ide (*Leuciscus idus melanotus*) after 3 days exposure was 10 PBT Assessment: Does not meet the criteria for bioaccumulation.
	Fatty acids, C8-C16, ethylhexyl ester	135800-37-2	6.31	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill Sunfish - 13 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 10 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 14.87 mg/L -48-hr LC_{50} *Daphnia magna* - 14 mg/L **Acute Aquatic Toxicity** -96-hr LC_{50} *Brachydanio rerio* ->100 [WAF] mg/L (biomass), 0.6 (growth rate), 0.025 (NOEC) -48-hr EL_{50} *Daphnia magna* - 12.41 mg/L -72-hr EL_{50} *Pseudokirchneriella subcapitata* - 39.7 [WAF] mg/L -72-day EL_{50} *Pseudokirchneriella subcapitata* -7.08 [WAF] mg/L **Chronic Toxicity** -No studies available **Terrestrial Toxicity** -No studies available **$PNEC_{water}$** - 0.001 mg/L **$PNEC_{soil}$** - 11 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: 6.68 to 8.65 PBT Assessment: Does not meet the criteria for bioaccumulation.

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Ethoxylated branched C13 alcohol	78330-21-9	Tier 1 (PBT/Exposure Assessment)	PBT Assessment: The overall conclusion is that Ethoxylated branched C13 alcohol is not a PBT substance. Qualitative Assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Ethylene glycol	107-21-1	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that ethylene glycol is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., kidney toxicity). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Fatty acids, C8-C16, ethylhexyl ester	135800-37-2	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Fatty acids, C8-C16, ethylhexyl ester is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Fatty acids, tall-oil, ethoxylated	61791-00-2	1.0	**Aquatic Toxicity** -96-hr LL_{50} *Brachydanio rerio ->100 [WAF]* mg/L -48-hr EL_{50} *Daphnia magna* - 12.41 mg/L -72-hr EL_{50} *Pseudokirchneriella subcapitata* - 39.7 [WAF] mg/L -72-day EL_{50} *Pseudokirchneriella subcapitata* -7.08 [WAF] mg/L **Chronic Toxicity** -No studies available **Terrestrial Toxicity** -No studies available **$PNEC_{water}$** - 0.12 mg/L **$PNEC_{soil}$** - 39 to > 683 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Skin sensitizer Ecological Hazard - Harmful to aquatic life. Harmful to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: PBT Assessment: Does not meet the criteria for bioaccumulation.
	Glutaraldehyde	111-30-8	0.0010	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill Sunfish - 13 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 10 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 14.87 mg/L -48-hr LC_{50} *Daphnia magna* - 14 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Scenedesmus subspicatus* - 0.375 mg/L (biomass), 0.6 (growth rate), 0.025 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.92 mg/L (biomass), 0.61 (growth rate), 0.33 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.61 mg/L (growth rate) Chronic Aquatic - Fish -97-day LOEC *Oncorhynchus mykiss* - 5 mg/L -97-day NOEC *Oncorhynchus mykiss* - 1.6 mg/L Chronic Aquatic - Invertebrate -21-day NOEC *Daphnia magna* - 5 mg/L **Terrestrial Toxicity** Earthworms -14-day LC50 - 500 mg/kg soil dry weight Soil microoganisms -28-day EC50 - 360 mg/kg soil dry weight - > 593 mg/kg soil dry weight -28-day EC10 - 1.5 mg/kg soil dry weight - 11.5 mg/kg soil dry weight Avian -single dose (oral gavage) LC50 Mallard duck - 206 mg/kg -5-day dietary NOEC - Mallard duck - >2500 ppm Terrestrial Plants: -19-day EC_{50} - *Avena sativa* (oats) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate, dry matter, shoot length) -19-day EC_{50} . *Brassica napus* (rapeseed) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 500 (dry matter), 250 (shoot length) -19-day EC_{50} - *Vicia sativa* (vetch) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 125 (dry matter), 125 (shoot length) **$PNEC_{water}$** - 0.0025 mg/L (Chronic algae) **$PNEC_{soil}$** -0.02 mg/kg soil dry weight (lChronic soil organisms)	Qualitative Assessment: Human Health Hazard - Corrosive; skin/respiratory sensitizer Ecological Hazard - Very toxic to aquatic life with long lasting effects. Low concern to terrestrial organisms. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Fatty acids, tall-oil, ethoxylated	61791-00-2	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Fatty acids, tall-oil, ethoxylated is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Glutaraldehyde	111-30-8	Tier 2	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment: The overall conclusion is that glutaraldehyde is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is readily biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to gluteraldehyde (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Glycerine	56-81-5	0.43	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 54,000 mg/L -96-hr LC_{50} sheepshead minnow- >11,000 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} *Daphnia magna* - >10,000 mg/L Acute Aquatic - Algae and other aquatic plants -8-day EC_{0} *Scenedesmus quadricauda* - >10,000 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 100 mg/L (Acute *Daphnia*) **$PNEC_{soil}$** - 1.3 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: -No bioconcentration studies conducted -Experimental log Kow of -1.75 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Guar gum	9000-30-0	667	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 218 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 42 mg/L -96-hr LC_{50} *Daphnia magna* - <6.2 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.006 mg/L (Acute *Daphnia*) **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern to fish, moderate acute toxicity to invertebrates PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Hydrochloric acid	7647-01-0	474	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - pH 4.12 (hard water), pH 3.98 (soft water) -96-hr LC_{50} *Lepomis macrochirus* - pH 3.25-3.5 Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - pH 4.92 Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Chlorella vulgaris* - pH 4.7 (growth rate), pH 4.82 (biomass), pH 5 (yield/growth rate) Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive; respiratory irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely PBT Assessment: Not applicable.	Environmental Fate Properties: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Glycerine	56-81-5	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that glycerine is not a PBT substance. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA
	Guar gum	9000-30-0	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - unlikely to cause harm to workers Environment -Potentially harmful to the environment in the event of transport spill NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) Qualitative assessment indicated low concern to human health. PBT Assessment - The overall conclusion is that guar gum is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Hydrochloric acid	7647-01-0	Tier 1 (NICNAS/ Qualitative Assessment/ PBT)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment - The overall conclusion is that hydrochloric acid is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Hydrotreated light petroleum distillate	64742-47-8	1.0	**$PNEC_{water}$** - 0.001 mg/L **$PNEC_{soil}$** - 17-100 mg/kg dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Toxic to aquatic life with long lasting effects. PBT Assessment: Not determined	Environmental Fate Properties: Inherently biodegradable PBT Assessment: Does meet the screening criteria for persistence	Environmental Fate Properties: log Kow > 10 PBT Assessment: Does meet the screening criteria for bioaccumulation.
	Hydroxylpropyl guar	39421-75-5	1.35	**Aquatic Toxicity -** no studies available **$PNEC_{water}$** - not derived **$PNEC_{soil}$ -** not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Not determined	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: not expected to bioaccumulate based on it's large molecular weight PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Iron gluconate	299-29-6	2.50	**Aquatic Toxicity** Acute Aquatic - Iron Gluconate (Seawater Species) -96-hr LC50 Scophthalmus mamimus - >1,000 mg/L -48-hr EC50 Acartia tonsa -296.2 mg/L -72-hr EC50 Skeletonema costatum - 265.7 mg/L Acute Aquatic - Sodium Gluconate -96-hr LC50 Oryzias latipes - >100 mg/L -48-hr EC50 Daphnia magna - >1,000 mg/L -72-hr EC50 Desmodesmus subspicatus - >1,000 mg/L **Chronic Toxicity** -No studies are available **Terrestrial Toxicity** -No studies are available PNECwater - 2.7 mg/L PNECsoil - 0.7 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: log Kow = -7.7 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Hydrotreated light petroleum distillate	64742-47-8	Tier 2	This chemical satisfies the PBT criteria for persistence and possibly for bioaccumulation. It is also considered toxic to aquatic life with long lasting effects. Therefore, a Tier 2 assessment was conducted for potential exposures to humans.	A quantitative risk characterisation, or the Margin of Exposure approach (MoE), was used to assess the health risk to workers from potential exposure to hydrotreated light petroleum distillate. The potential for adverse effects decreases as the MoE increases. According to the guidance, an MoE is of low concern for human health if it is 100 or greater. The MoEs calculated were greater than this threshold (**Appendix E**). Therefore, the chemical is of low concern for workers.
	Hydroxylpropyl guar	39421-75-5	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment - The overall conclusion is that hydroxylpropyl guar is unlikely to be a PBT substance because of physio-chemical properties. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA
	Iron gluconate	299-29-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment - The overall conclusion is that hydrochloric acid is not a PBT substance. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Methanol	67-56-1	4.0	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill - 15,400 mg/L -96-hr LC_{50} *Salmo gairdneri* - 20,100 mg/L -96-hr LC_{50} *Pimphales promelas* - 28,100 mg/L Acute Aquatic - Invertebrate -96-hr EC_{50} *Daphnia magna* - 18,620 mg/L -48-hr EC_{50} *Daphnia magna* - >10,620 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr EC_{50} *Selenastrum capricornutum* -~22,000 mg/L -10-14 d EC_{50} *Chlorella pyrenoidosa* - 28,400 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** 35-d EC_{50} Earthworm *Eisenia fetida* - 17,199 mg/kg soil dw 63-d EC_{50} Earthworm *Eisenia fetida* - 26,646 mg/kg soil dw 28-d EC_{25} *Folsomia candida* - 2,842 mg/kg soil dw (test results) 28-d NOEC (reproduction) *Folsomia candida* - 1,000 mg/kg soil dw (derived graphically) 14-d EC_{50} *Hordeum vulgare* - 15,492 mg/kg soil dw 14-d NOEC (seedline emergence) *Hordeum vulgare* - 12,000 mg/kg soil dw (derived graphically) 14-d EC_{25} *Hordeum vulgare* - 2,538 mg/kg soil dw (test results) 14-d NOEC (shoot dry mass) *Hordeum vulgare* - 1,555 mg/kg soil dw (derived graphically) 14-d EC_{25} *Hordeum vulgare* - 2,823 mg/kg soil dw (test results) 14-d NOEC (root dry mass) *Hordeum vulgare* - 2,592 mg/kg soil dw (derived graphically) 14-d EC_{25} *Hordeum vulgare* - 4,885 mg/kg soil dw (test results) 14-d NOEC (shoot length) *Hordeum vulgare* - 2,592 mg/kg soil dw (derived graphically) 14-d EC_{25} *Hordeum vulgare* - 5,752 mg/kg soil dw (test results) 14-d NOEC (rott length length) *Hordeum vulgare* - 4,320 mg/kg soil dw (derived graphically) **$PNEC_{water}$** - 10 mg/L (Acute *Daphnia)* **$PNEC_{soil}$** - 6.3 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern if used at <3% Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: -Calculated log Kow -1.36 -BCF in *Cyprinus carpio* 1.0, BCF *Leuciscus idus* <10 PBT Assessment: Does not meet the criteria for bioaccumulation.
	Polyethylene glycol	25322-68-3	16	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Poecilia reticulata* - PEG (molecular weight unknown) >100 mg/L -96-hr LC_{50} *Pimphales promelas* - TetraEG (CAS No. 112-60-7) >10,000 mg/L -96-hr LC_{50} *Pimphales promelas* - PentaEG (CAS No. 4792-15-8) >50,000 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - TetraEG (CAS No. 112-60-7) 7,746 mg/L -48-hr EC_{50} *Daphnia magna* -PentaEG (CAS No. 4792-15-8) >20,000 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* ->100 mg/L -NOEC *Pseudokirchneriella subcapitata*- 100 mg/L Chronic Aquatic -No chronic studies available for low molecular weight PEGs -7-d NOEC *Pimphales promelas* (fish) - Triethylene Glycol (TEG, CAS No. 112-60-7) - 15,380 mg/L (weight) -7-d NOEC *Daphnia magna* (invertebrate) - Triethylene Glycol (TEG, CAS No. 112-60-7) - 8,590 mg/L (reproduction) **Terrestrial Toxicity** No terrestrial toxicity studies **$PNEC_{water}$** - 10 mg/L (chronic algae) **$PNEC_{soil}$** - 1.3 mg/kg soil dw (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradable. PBT Assessment: Does meet the screening criteria for persistence.	Environmental Fate Properties: -Calculated log Kow -0.958 -Estimated BCF for major PEG constituents ranges is 3.162 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Methanol	67-56-1	Tier 1 (NICNAS/ Qualitative Assessment/ PBT)	NICNAS Assessment (2018) Human Health - potentially harmful to public in event of transport spill or pond leak - potentially harmful to workers when mixing and/or cleaning or in event of industrial accident Environment -unlikely to cause harm to environment PBT Assessment: The overall conclusion is that methanol is not a PBT substance. Qualitative assessment indicated low concern to human health Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Polyethylene glycol	25322-68-3	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Polyethylene glycol is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Polypropylene glycol	25322-69-4	0.353	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Danio rerio* - >100 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 105.8 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Desmodesmus subspicatus* ->100 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No terrestrial toxicity studies **$PNEC_{water}$** - 0.2 mg/L (NOEC for Dapnia) **$PNEC_{soil}$** - 0.05 mg/kg soil dw (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: log Kow <0.3 to 0.9 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Potassium chloride	7447-40-7	8.272	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimpephelas promelas* - 880 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* 660 mg/L -48-hr EC_{50} *Ceriodaphnia dubia* - 630 mg/L Acute Aquatic - Algae and other plants -72-hr EC_{50} *Scenedesmus subspicatus* - >100 mg/L **Chronic Aquatic - Invertebrate** -7-day NOEC in a fathead minnow is 500 mg/L **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 1 mg/L (algae) **$PNEC_{soil}$** -not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Will dissociate to potassium and chloride ions which are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Propylene glycol n-propyl ether	1569-01-3	1.0	**Aquatic Toxicity** -96-hr LC_{50} *Oncorhynchus mykiss* - >100 mg/L -48-hr EC_{50} *Daphnia magna* - >100 mg/L -72-hr EC_{50} *Pseudokirchnierella subcapitata* - 3,440 mg/L **Chronic Toxicity** -No data available **Terrestrial Toxicity** -No data available **$PNEC_{water}$** - 1.0 mg/L **$PNEC_{soil}$** - 0.03 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Eye irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does meet the screening criteria for persistence.	Environmental Fate Properties: 0.621 (calculated) PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Silica dioxide	112926-00-8	0.003	**$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: bioaccumulation unlikely to occur PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Polypropylene glycol	25322-69-4	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Polypropylene glycol is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Potassium chloride	7447-40-7	Tier 1	PBT Assessment: The overall conclusion is that Potassium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Propylene glycol n-propyl ether	1569-01-3	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Propylene glycol n-propyl ether is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., eye irritant). Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Silica dioxide	112926-00-8	Tier 1 (NICNAS/ Qualitative Assessment/ PBT)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - unlikely to cause harm to workers Environment -unlikely to cause harm to environment PBT Assessment: The overall conclusion is that silica dioxide n-propyl ether is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Sodium bicarbonate	144-55-8	1.93	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 7,700 mg/L -96-hr LC_{50} *Lepomis macrochirus* - 7,100 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 4,100 mg/L -48-hr EC_{50} *Daphnia magna* - 1,640 mg/L -48-hr EC_{50} *Daphnia magna* - 1,020 mg/L Chronic Aquatic - Invertebrate -21-day NOEC Dapnia (reproduction) - >576 mg/L **Terrestrial Toxicity** -48-hr LC50 - acute honeybee test >24 µg/bee -48 hr NOEC - acute honeybee test 24µg/bee **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Na+ and HCO3- ions will not adsorb on particulate matter or surfaces and will not accumulate in living tissues. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium bisulfite	7631-90-5	47	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} (Potassium sulfite) *Leuciscus idus* - 316 mg/L -96-hr LC_{50} (Sodium pyrosulfite) *Salmo gairdneri* - 147-215 mg/L -96-hr LC_{50} (Potassium metabisulfite) *Brachydanio rerio* - 147-215 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} (Sodium disulfite) *Daphnia magna* - 88.8 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr EC_{50} (Sodium disulfite) *S. subspicatus* - 43.9 mg/L -72-hr EC_{10} (Sodium disulfite) *S. subspicatus* - 33.3 mg/L Chronic Aquatic - fish -34-day NOEC (Sodium sulfite) *Danio rerio* - >316 mg/L Chronic Aquatic - Invertebrate -21-day NOEC (Sodium sulfite) *Dapnia magna* - >10 mg/L **Terrestrial Toxicity** No terrestrial studies located. **$PNEC_{water}$** - 0.8 mg/L (Chronic Daphnia) **PNEC** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Sodium bisulfite is not expected to bioaccumulate in the environment because of its dissociation to ionic species and a gas. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium carbonate	497-19-8	0.002	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill sunfish - 300 mg/L -96-hr LC_{50} Mosquitofish - 740 mg/L -24-hr LC_{50} Bluegill sunfish - 385 mg/L -50-hr LC_{50} Molly - 297 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Ceriodaphnia dubia* - 200 - 227 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Eye irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Sodium carbonate is not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Sodium bicarbonate	144-55-8	Tier 1 (NICNAS/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that sodium bicarbonate is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium bisulfite	7631-90-5	Tier 1 (PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that sodium bisulfite is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is dissociates completely in aqueous media, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium carbonate	497-19-8	Tier 1 (NICNAS/PBT)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - potentially harmful to workers in event of industrial accident Environment -unlikely to cause harm to environment PBT Assessment: The overall conclusion is that sodium carbonate is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., irritant). Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Sodium Chloride	7647-14-5	0.91	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 *Lepomis macrochirus* - 5,840 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 1,900 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr NOEC *Lemna* - 6,780 mg/L **Chronic Toxicity** Chronic Aquatic - Fish 33-day NOEC - *Pimephales promelas* - 232 mg/L Chronic Aquatic - Invertebrate 21-day NOEC - *Daphnia pulex* - 314 mg/L **Terrestrial Toxicity** -14-day LC50 *E. fetida* - 3296 mg/kg soil dw -10-week NOEC *E. fetida* - 3,507 mg/kg soil -7-day EC50 - red fescue grass - 500.8 mg/kg soil -12-hr LD50 - wild house sparrow - 3,000 - 3,500 mg/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Essential ions to biological systems. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium diacetate	126-96-5	13.0	**Aquatic Toxicity** - on Sodium Acetate and Potassium Acetate -96-hr LC_{50} Brachydanio rerio - >100 mg/L -48-hr EC_{50} *Daphnia magna* - Sodium acetate - >1,000 and 1,730* mg/L. *Values converted to sodium diacetate using the molecular weights of sodium acetate (82.03 g/mol), potassium acetate (98.15 g/mol), and sodium diacetate (142.09g/mol). -48-hr EC50 Daphnia magna - Potassium acetate - >459.5 and 665* mg/L. *Values converted to sodium diacetate using the molecular weights of sodium acetate (82.03 g/mol), potassium acetate (98.15 g/mol), and sodium diacetate (142.09 g/mol). -72-hr EC_{50} *Skeletonema costatum* - >500 and 724* mg/L *Values converted to sodium diacetate using the molecular weights of sodium acetate (82.03 g/mol), potassium acetate (98.15 g/mol), and sodium diacetate (142.09 g/mol). **Chronic Aquatic - Algae and other aquatic plants** No studies are available. **Terrestrial Toxicity** No studies are available. **$PNEC_{water}$** - 1.7 mg/L **$PNEC_{soil}$** - 0.02 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Severe eye irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: log Kow = -3.72 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium hydroxide	1310-73-2	126	**Aquatic Toxicity** Acute Aquatic - Fish -24-hr LC50 *Carassius auratus* - 160 mg/L -48-hr LC50 *Leuciscus idus melanotus* - 189 mg/L -96-hr LC50 *Gambusia affinis* - 125 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Ceriodaphnia cf. dubia* - 40 mg/L -toxicity threshold of sodium hydroxide for Daphnia magna - 40 mg/L ot 240 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Sodium hydroxide is not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium iodide	7681-82-5	1.0	**Aquatic Toxicity** Acute Aquatic -48-hr EC_{50} *Daphnia magna* - 0.17 mg/L -96-hr LC_{50} Danio rerio - >100 mg/L **Chronic Toxicity -** -21-day NOEC in a Daphnia reproduction test is 91 mg/L (ECHA) [KI. score = 2]. In another Daphnia reproduction test, the 21-day NOEC was 14 mg/L (ECHA) [KI. score = 2]. -8-day LOEC to green algae Scenedesmus quadricauda was 2,370 mg/L (ECHA) [KI. score = 2]. **Terrestrial Toxicity** No studies are available **$PNEC_{water}$** - 0.0034 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Skin/eye irritant. Repeated exposures may cause thyroid gland toxicity. Ecological Hazard - Very toxic to aquatic life PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Not applicable PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Sodium Chloride	7647-14-5	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Technical report number 11 (NICNAS, 2017). In Technical report number 14, releases to surface waters were found to have limited long-term environmetnal effects because sodium chloride is ubiquitous and present in most water, soil, and sediment. Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium diacetate	126-96-5	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that sodium bicarbonate is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium hydroxide	1310-73-2	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that sodium hydroxide is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium iodide	7681-82-5	Tier 1 (PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that sodium iodide is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Sodium perborate tetrahydrate	10486-00-7	1.02	**Aquatic Toxicity** Chronic Aquatic - Fish -32-day LOEC - *Oncorhynchus mykiss* 0.04 mg/L to 27.6 mg/L -87-day NOEC - *Oncorhynchus mykiss* 2.1 mg/L Chronic Aquatic - Invertebrate -21-day MATC - *Daphnia magna* 4.665 mg/L -21-day LC_{50} - *Daphnia magna* 6 mg/L Chronic Aquatic - Algae and other aquatic plants 14-day NOEC- *Chlorella pyrenoidosa* 0.4 mg/L 14-day NOEC- *Chlorella vulgaris* 5.2 mg/L **PNECwater** - 0.37 mg/L (ANZECC water quality guideline) **PNECsoil** - not derived	Qualitative Assessment: Human Health Hazard - Severe eye irritant; known or presumed human reproductive toxicant. Ecological Hazard - moderate concern. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Persistence criteria are not applicable.	Environmental Fate Properties: BCF < 0.1 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium persulfate	7775-27-1	25	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} - *Oncorhynchus mykiss* 163 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} - *Daphnia magna* 133 mg/L Acute Aquatic - Algae and other aquatic plants *2-hr LC50 - Selenastrum capricornutum* 116 mg/L No chronic studies available. **PNECwater** - 1.2 mg/L (acute algae) **PNECsoil** - not derived	Qualitative Assessment: Human Health Hazard - Skin and respiratory sensitizer; irritant Ecological Hazard -low concern. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Persistence criteria are not applicable.	Environmental Fate Properties: Dissociates to ions that are ubiquitous in environment PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium polyacrylate	9003-04-7	0.33	**Aquatic Toxicity** toxicity studies for MW 4,500 shown because these MW polymers are most commonly used for detergents. For additional toxicity studies, refer to the dossier. Acute Aquatic - Fish -96-hr LC_{50} - *Lepomis macrochirus* >1,000 mg/L -96-hr LC_{50} - *Lepomis macrochirus* >1,000 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} - *Daphnia magna* >200 mg/L -48-hr EC_{50} - *Daphnia magna* >1,000 mg/L Chronic Aquatic - Fish -32-d NOEC - *Pimephales promelas* 56 mg/L -28-d NOEC - *Brachydanio rerio* >450 mg/L Chronic Aquatic - Invertebrate -21-d NOEC - *Daphnia magna* >450 mg/L -21-d NOEC - *Daphnia magna* 58 mg/L -21-d NOEC - *Daphnia magna* 12 mg/L Chronic Aquatic - Algae and other aquatic plants -96-hr NOEC *Scenedesmus. subspicatus* - 480 mg/L **Terrestrial Toxicity** -14-d EC0 - (4,500 Mean MW sodium polyacrylate) Eisenia foetida foetida 1,000 mg/L -28-d EC10 - (4,500 Mean MW sodium polyacrylate) Nitrogen transformation (soil microorganisms) >2,500 mg/L -28-d EC10 - (4,500 Mean MW sodium polyacrylate) Carbon transformation (soil microorganisms) >2,500 mg/L **$PNEC_{water}$** - 1.2 mg/L (lChronic Daphnia) **$PNEC_{soil}$** - 25 mg/kg soil dry weight (lChronic soil microogranisms)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not biodegradable. PBT Assessment: Does meet the screening criteria for persistence.	Environmental Fate Properties: Due to their high molecular weights, sodium polyacrylates are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Sodium perborate tetrahydrate	10486-00-7	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Sodium perborate tetrahydrate is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media, does not bioaccumulate, and does not meet the PBT toxicity criteria. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium persulfate	7775-27-1	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Sodium persulfateis not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium polyacrylate	9003-04-7	Tier 1 (NICNAS/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that sodium polyacrylates are not PBT substances. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Sodium Sulfate	7757-82-6	0.01	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Pimephales promelas 7,960 mg/L Acute Aquatic - Invertebrate -48-hr EC50 - *Daphnia magna* - 4,736 mg/L Chronic Aquatic - Invertebrate -7-day - $LOEC_{50}$ - *Ceriodapnia dubia* 1,329 mg/l **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 11 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the criteria for biodegradation.	Environmental Fate Properties: Dissociates to ions that are ubiquitous in environment PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium Sulfite	7757-83-7	0.0043	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Golden Orfe - 316 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 89* (59) mg/L -72-hr LC_{50} *Desmodesmus subspicatus* - 43.8* (29)mg/L * test substance sodium disulfite; adjusted concentration for sodium sulfite in parentheses **Chronic Toxicity** -34-day NOEC zebra fish >316 mg/L. -21-day NOEC *Daphnia magna* >10* (6.6) mg/L EC_{10} *Desmodesmus subspicatus* 33.3* (22) mg/L * test substance sodium disulfite; adjusted concentration for sodium sulfite in parentheses **Terrestrial Toxicity** No adequate studies were located. **$PNEC_{water}$** - 0.7 mg/L (NOEC for invertebrates) **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the criteria for biodegradation.	Environmental Fate Properties: Dissociates to ions that are ubiquitous in environment PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium thiosulfate	7772-98-7	0.94	**Aquatic Toxicity** Acute Aquatic -96-hr LC_{50} *Lepomis macrochirus* - 510 mg/L -96-hr LC_{50} *Salmo gairdneri* - 770 mg/L -72-hr EC_{50} Pseudokirchneriella subcapitata - >100 mg/L -48-hr EC_{50} *Daphnia magna* - 230 mg/L **Chronic Studies** - No data are available. **Terrestrial Toxicity** - No studies are available **$PNEC_{water}$** - 1.0 mg/L **$PNEC_{soil}$** - No data available	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the criteria for biodegradation.	Environmental Fate Properties: Dissociates to ions that are ubiquitous in environment PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Sodium Sulfate	7757-82-6	Tier 1 (PBT)	PBT Assessment: The overall conclusion is that Sodium Sulfate not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium Sulfite	7757-83-7	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that Sodium Sulfite not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium thiosulfate	7772-98-7	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that Sodium thiosulfate not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Sorbitan, mono-9-octadecenoate, (Z)	1338-43-8	13	**Aquatic Toxicity** -96-hr LL_{50} *Salmo gairdneri* - >1,000 [WAF] mg/L -96-hr LL_{50} *Oryzias latipes* - >1,000 [WAF] mg/L -48-hr EL_{50} *Daphnia magna* - >1,000 [WAF] mg/L -72-hr EL_{50} *Pseudokirchneriella subcapitata* - >1,000 [WAF] mg/L **Chronic Aquatic - Invertebrate** -21-day NOELR (no-observed-effect-loading-rate) in a *Daphnia* reproduction test for sorbitan stearate (CAS No. 1338-41-6) is 16 mg/L WAFA (ECHA) [Kl. score = 2]. -72-hr NOELR (no-observed-effect-loading-rate) to *Pseudokirschneriella subcapitata* for sorbitan stearate was 560 mg/L [WAF] (ECHA) [Kl. score = 1]. **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 0.32 mg/L WAF **$PNEC_{soil}$** -10 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sorbitan monooleate polyoxyethylene derivative	9005-65-6	13.0	**Aquatic Toxicity** Acute Aquatic -72-hr EL_{50} *Pseudokirchneriella subcapitata* - 58.84 [WAF] mg/L -96-hr LL_{50} Brachydanio rerio - >100 [WAF] mg/L **Chronic Toxicity -** -21-day NOELR (No-Observed-Effect-Loading-Rate) for sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5] in a Daphnia reproduction test was 10 mg/L WAF (ECHA) [Kl. score = 2]. -72-hr EL10 for sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5] to Pseudokirchneriella subcapitata is 19.05 mg/L WAF (ECHA) [Kl. score = 2]. **Terrestrial Toxicity** No studies are available **$PNEC_{water}$** - 0.2 mg/L **$PNEC_{soil}$** - 2.1 to 3.4 mg/kg soil dry weight.	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: 5.19 - 5.89 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Tributyl tetradecyl phosphonium chloride	81741-28-8	28	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill sunfish - 0.0586 mg/L -96-hr LC_{50} Common carp - 0.087 mg/L -96-hr LC_{50} Rainbow trout - 0.490 mg/L -96-hr LC_{50} Rainbow trout - 0.200 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 0.0252 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Selenastrum capricornutum* - 0.019 mg/L **Terrestrial Toxicity** -8-d dietary LC_{50} Bobwhite Quail 4,215 ppm -8-d dietary NOEC Bobwhite Quail 1,980 ppm -8-d dietary LC50 Mallard Duck 3,663 ppm -8-d dietary NOEL Mallard Duck 1,780 ppm -14-d oral gavage LD50 Mallard Duck 232 mg/kg -14-d oral gavage NOEL Mallard Duck <178 mg/kg **$PNEC_{water}$** -0.000019 mg/L (Acute algae) **$PNEC_{soil}$** - 13 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Corrosive; very high acute inhalation toxicity Ecological Hazard - Very toxic to aquatic life. Very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradable PBT Assessment: Does meet the screening criteria for persistence.	Environmental Fate Properties: No bioaccumulation studies are available on TTPC. Log Kow - 2.45 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Sorbitan, mono-9-octadecenoate, (Z)	1338-43-8	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Sorbitan monooleate polyoxyethylene derivative is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Sorbitan monooleate polyoxyethylene derivative	9005-65-6	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that Sorbitan monooleate polyoxyethylene derivative is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure.	NA
	Tributyl tetradecyl phosphonium chloride	81741-28-8	Tier 2	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -Limited assessment - detailed information unavailable therefore, chemical assessed at earliest most conservative level of testing, which overestimates risk. Therefore, classified as potentially harmful at this level, but further information and testing wold be required to determine actual level of risk PBT Assessment: The overall conclusion is that TTPC is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to Tributyl tetradecyl phosphonium chloride (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.

Table 1
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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Mar-20	Triethanol amine	102-71-6	0.47	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimephales promelas* - 11,800 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Ceriodaphnia dubia* - 610 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Desmodesmus subspicatus* - 512 mg/L (neutralised), 216 (un-neutralised) -EC_{10} - *Desmodesmus subspicatus* 26 mg/L (neutralised) Chronic Aquatic -21 day NOEC Daphnia 16 mg/L (mortality), 125 mg/L (reproduction rate), 250 mg/L (reproduction on appearance of first offspring) **Terrestrial Toxicity** No studies available **PNECwater** -0.32 mg/L (lowest EC_{10} daphnia) **PNECsoil** - 0.04 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: log Kow = -1.9 (experimental) PBT Assessment: Does meet the screening criteria for bioaccumulation.
	Ulexite	1319-33-1	209	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 Fathead minnow 79.7 mg B/L Aquatic Invertebrate -48-hr Freshwater invertebrates 64 - > 544 mg B/L Aquatic Algae -72-hr EC50 *Pseudokirchneriella subcapitata* 52.4 mg B/L Chronic Aquatic - Fish -4-day EC10 *Microp salmoides 36.8* mg B/L -long term NOEC-LOEC *Pimephales promelas* 21.3 mg B/L -long term NOEC-LOEC Brachydanio rerio - 36 mg/L Chronic Aquatic - Invertebrate -NOEC *Daphnia magna* - 13.9 mg B/L -NOEC Hyalella azteca - 6.3 mg B/L Chronic Aquatic - Algae and aquatic plants -NOEC *Brachionus calyciflorus* 24.6 mg B/L -NOEC *Lampsilis siliquoidea* - 30 mg B/L **Terrestrial Toxicity** -NOEC ranging from 7.2 mgB/kg dw to 86.7 mg B/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Envrionmental Fate Properties: naturally occuring mineral; not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Mar-20	Triethanol amine	102-71-6	Tier 1 (Qualitative/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that Triethanol amine is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. A Tier 2 assessment is not warranted.	NA
	Ulexite	1319-33-1	Tier 1	PBT Assessment: The overall conclusion is that Ulexite is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Ceramic Materials and wares, chemicals	66402-68-4	1199.35	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Hazard: low concern Ecological Hazard: low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant as substance is inorganic PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Not relevant as substance is inorganic PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Crystalline silica, quartz	14808-60-7	47.62	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Hazard: Inhalation: silicosis and lung cancer in humans. Oral/dermal: low concern. Ecological Hazard: Low concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: inorganic complex not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Guar gum	9000-30-0	14.55	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 218 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 42 mg/L -96-hr LC_{50} *Daphnia magna* - <6.2 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.006 mg/L (Acute *Daphnia*) **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern to fish, moderate acute toxicity to invertebrates PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Choline Chloride (2-hydroxy-N,N,N-trimethylethanaminium chloride)	67-48-1	12.04	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oryzias latipes* - >100 mg/L (nominal and measured) -96-hr LC_{50} *Leuciscus idus* - >10,000 mg/L (78% solution of choline chloride) Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 349 mg/L (nominal and measured) -48-hr EC_{50} *Daphnia magna* - >500 mg/L (78% solution of choline chloride) Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - >1,000 (nominal and measured) Chronic Aquatic - Invertebrate -21-day *Daphnia magna* reproduction test NOEC 30.2 mg/L (nominal and measured) Chronic Aquatic - Algae and other aquatic plants -72-hr *Pseudokirchneriella subcapitata* study NOEC 30.2 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.3 mg/L **$PNEC_{soil}$** - 0.007 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Experimental log Kow is -3.77 PBT Assessment: Does not meet the criteria for bioaccumulation.

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Ceramic Materials and wares, chemicals	66402-68-4	Tier 1 (Qualitative Assesment/PBT)	PBT Assessment: The overall conclusion is that Ceramic Materials and wares, chemicals is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Crystalline silica, quartz	14808-60-7	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Crystalline silica, quartz is not a PBT substance. Qualitative Assessment indicated hazardous to human health by the inhalation pathway; not hazardous by the oral/dermal route. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore a Tier 2 Assessment is not warranted.	NA
	Guar gum	9000-30-0	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - unlikely to cause harm to workers Environment -Potentially harmful to the environment in the event of transport spill NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) Qualitative assessment indicated low concern to human health. PBT Assessment - The overall conclusion is that guar gum is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Choline Chloride (2-hydroxy-N,N,N-trimethylethanaminium chloride)	67-48-1	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that choline chloride is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Acrylamide/ammonium acrylate copolymer	26100-47-0	5.78	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Not expected to bioaccumulate because of poor water solubility and high molecular weight PBT Assessment: Does not meet criteria for bioaccumulation
	Ethylene glycol	107-21-1	2.93	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimephales promelas* - >72,860 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 22,810 mg/L and 24,591 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - >100 mg/L, 46,300 mg/L (20°C), 51,000 mg/L (24°C) -48-hr EC50 *Ceriodaphnia dubia-affinis* - 25,800 mg/L (20°C), 10,000 mg/L (24°C) Acute Aquatic - Algae and other aquatic plants -96-hr IC_{50} *Selenastrum capricornutum* - 10,940 mg/L -96-hr NOEC *Selenastrum capricornutum* - 10,000 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L Chronic Aquatic - Algae -72-hr NOEC *Pseudokirchneriella subcapitata* - >100 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 10 mg/L **$PNEC_{soil}$** - 0.13 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Repeated exposures may cause kidney toxicity Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: -Calculated log Kow is -1.36 -BCF in golden ide (*Leuciscus idus melanotus*) after 3 days exposure was 10 PBT Assessment: Does not meet the criteria for bioaccumulation.
	Hydrochloric acid	7647-01-0	3.55	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - pH 4.12 (hard water), pH 3.98 (soft water) -96-hr LC_{50} *Lepomis macrochirus* - pH 3.25-3.5 Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - pH 4.92 Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Chlorella vulgaris* - pH 4.7 (growth rate), pH 4.82 (biomass), pH 5 (yield/growth rate) Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive; respiratory irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely PBT Assessment: Not applicable.	Environmental Fate Property: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Hydrotreated light petroleum distillate	64742-47-8	3.15	**$PNEC_{water}$** - 0.001 mg/L **$PNEC_{soil}$** - 17-100 mg/kg dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Toxic to aquatic life with long lasting effects. PBT Assessment: Not determined	Environmental Fate Properties: Inherently biodegradable PBT Assessment: Does meet the screening criteria for persistence	Environmental Fate Property: log Kow > 10 PBT Assessment: Does meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Acrylamide/ammonium acrylate copolymer	26100-47-0	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that choline chloride is not a PBT substance. Management: No additional management required, Tier 1 screening satisfied.	NA
	Ethylene glycol	107-21-1	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that ethylene glycol is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., kidney toxicity). Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Hydrochloric acid	7647-01-0	Tier 1 (NICNAS/ Qualitative Assessment/ PBT)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment - The overall conclusion is that hydrochloric acid is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Hydrotreated light petroleum distillate	64742-47-8	Tier 2	This chemical satisfies the PBT criteria for persistence and possibly for bioaccumulation. It is also considered toxic to aquatic life with long lasting effects. Therefore, a Tier 2 assessment was conducted for potential exposures to humans.	A quantitative risk characterisation, or the Margin of Exposure approach (MoE), was used to assess the health risk to workers from potential exposure to hydrotreated light petroleum distillate. The potential for adverse effects decreases as the MoE increases. According to the guidance, an MoE is of low concern for human health if it is 100 or greater. The MoEs calculated were greater than this threshold (**Appendix E**). Therefore, the chemical is of low concern for workers.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Ulexite	1319-33-1	2.31	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 Fathead minnow 79.7 mg B/L Aquatic Invertebrate -48-hr Freshwater invertebrates 64 - > 544 mg B/L Aquatic Algae -72-hr EC50 *Pseudokirchneriella subcapitata* 52.4 mg B/L Chronic Aquatic - Fish -4-day EC10 *Microp salmoides 36.8* mg B/L -long term NOEC-LOEC *Pimephales promelas* 21.3 mg B/L -long term NOEC-LOEC Brachydanio rerio - 36 mg/L Chronic Aquatic - Invertebrate -NOEC *Daphnia magna* - 13.9 mg B/L -NOEC Hyalella azteca - 6.3 mg B/L Chronic Aquatic - Algae and aquatic plants -NOEC *Brachionus calyciflorus* 24.6 mg B/L -NOEC *Lampsilis siliquoidea* - 30 mg B/L **Terrestrial Toxicity** -NOEC ranging from 7.2 mgB/kg dw to 86.7 mg B/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Envrionmental Fate Property: Naturally occuring mineral; not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy	31726-34-8	1.93	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Oncorhynchus mykiss - 1,464 mg/L -96-hr LC_{50} *Pimephales promelas* - range from 1,580 mmg/L - 2,137 mg/L -96 hr LC_{50} - Lepomis machrochirus - 1,490 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - range from - 881 mg/L - 2,650 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - 911 mg/L (biomass); 88 mg/L -72-hr EC_{50} *Selenastrum capricornutum* - 720 mg/L (biomass); 280 mg/L **Chronic Toxicity** Chronic Aquatic - Fish -21-day NOEC *Brachydanio rerio* - > 100 mg/L Chronic Aquatic - Invertebrate - 21-day NOEC *Daphnia magna* - 100 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 8.8 mg/L **$PNEC_{soil}$** - 0.9 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is 2.9 No bioconcentration studies PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Ulexite	1319-33-1	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that ulexite is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy	31726-34-8	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt	129898-01-7	1.49	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Rianbow Trout - >1,000 mg/L -96-hr LC_{50} Zebra Fish - >1,000 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} Daphnia - 320 mg/L -72-hr EC_{50} - 130 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - 0.13 mg/L **$PNEC_{sediment}$ & $PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - Low toxicity concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Meets 150 day critierion for ultimate biodegradability. PBT Assessment: Meets the screening criteria for persistence	Environmental Fate Property: Not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium hydroxide	1310-73-2	1.22	**Aquatic Toxicity** Acute Aquatic - Fish -24-hr LC50 *Carassius auratus* - 160 mg/L -48-hr LC50 *Leuciscus idus melanotus* - 189 mg/L -96-hr LC50 *Gambusia affinis* - 125 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Ceriodaphnia cf. dubia* - 40 mg/L -toxicity threshold of sodium hydroxide for Daphnia magna - 40 mg/L ot 240 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Property: Sodium hydroxide is not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Distillates (petroleum), solvent-dewaxed heavy paraffinic	64742-65-0	1.40	**Aquatic Toxicity** Acute Aquatic Fish - 96 hour LC_{50} fish > 100 mg/L Acute Aquatic Invertebrate - 48 hour LC_{50} >10,000 mg/L Acute Aquatic Algae -72-hour NOEL ≥ 100 mg/L **Chronic Toxicity** Chronic Aquatic - Infertebrates -21 day NOEL - *Daphnia magna* - 100 mg/L [WAF] -21-day - NOEL - *Daphnia magna* - >1000 mg/L -21 day - NOEL - *Daphnia magna* - 10 mg/L **Terrestrial Toxicity** No terrestrial data found **$PNEC_{water}$** - 1 mg/L **$PNEC_{soil}$** - 4000 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradable PBT Assessment: Does meet the screening criteria for persistence	Environmental Fate Property: Not available because UVCB Substance PBT Assessment: Not applicable
	Diammonium peroxidisulphate	7727-54-0	0.588	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 76.3 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 120 mg/L Acute Aquatic - Algae -72-hr EC_{10} *Phaedactylum tricornutum* - 320 mg/L Chronic Aquatic - Invertebrate -21-day NOEC *Daphnia magna* 20.8 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - 0.076 mgL **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Moderate concern (irigating to eyes, skin, and respiratory tract) Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Inorganic salt that dissolves to respective cations and anions. PBT Assessment: Does not meet the screening criteria for bioaccumulation. Diammonium peroxidisulphate is not a PBT substance

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt	129898-01-7	Tier 1 (Qualitative/PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that 2-propenoic acid, polymer with sodium phosphinate is not a PBT substance. Qualitative Assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is ultimately biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Sodium hydroxide	1310-73-2	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that sodium hydroxide is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Distillates (petroleum), solvent-dewaxed heavy paraffinic	64742-65-0	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that ulexite is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is inherently biodegradeable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Diammonium peroxidisulphate	7727-54-0	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that diammonium peroxodisulphate is not a PBT substance. Qualitative assessment indicated potential human hazard (e.g., skin, eye, and respiratory irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is dissociates completely, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Glutaraldehyde	111-30-8	1.00	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill Sunfish - 13 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 10 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 14.87 mg/L -48-hr LC_{50} *Daphnia magna* - 14 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Scenedesmus subspicatus* - 0.375 mg/L (biomass), 0.6 (growth rate), 0.025 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.92 mg/L (biomass), 0.61 (growth rate), 0.33 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.61 mg/L (growth rate) Chronic Aquatic - Fish -97-day LOEC *Oncorhynchus mykiss* - 5 mg/L -97-day NOEC *Oncorhynchus mykiss* - 1.6 mg/L Chronic Aquatic - Invertebrate -21-day NOEC *Daphnia magna* - 5 mg/L **Terrestrial Toxicity** Earthworms -14-day LC50 - 500 mg/kg soil dry weight Soil microoganisms -28-day EC50 - 360 mg/kg soil dry weight - > 593 mg/kg soil dry weight -28-day EC10 - 1.5 mg/kg soil dry weight - 11.5 mg/kg soil dry weight Avian -single dose (oral gavage) LC50 Mallard duck - 206 mg/kg -5-day dietary NOEC - Mallard duck - >2500 ppm Terrestrial Plants: -19-day EC_{50} - *Avena sativa* (oats) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate, dry matter, shoot length) -19-day EC_{50} - *Brassica napus* (rapeseed) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 500 (dry matter), 250 (shoot length) -19-day EC_{50} - *Vicia sativa* (vetch) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 125 (dry matter), 125 (shoot length) **$PNEC_{water}$** - 0.0025 mg/L (Chronic algae) **$PNEC_{soil}$** -0.02 mg/kg soil dry weight (IChronic soil organisms)	Qualitative Assessment: Human Health Hazard - Corrosive; skin/respiratory sensitizer Ecological Hazard - Very toxic to aquatic life with long lasting effects. Low concern to terrestrial organisms. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sorbitan, mono-9-octadecenoate, (Z)	1338-43-8	0.53	**Aquatic Toxicity** -96-hr LL_{50} *Salmo gairdneri* - >1,000 [WAF] mg/L -96-hr LL_{50} *Oryzias latipes* - >1,000 [WAF] mg/L -48-hr EL_{50} *Daphnia magna* - >1,000 [WAF] mg/L -72-hr EL_{50} *Pseudokirchneriella subcapitata* - >1,000 [WAF] mg/L **Chronic Aquatic - Invertebrate** -21-day NOELR (no-observed-effect-loading-rate) in a *Daphnia* reproduction test for sorbitan stearate (CAS No. 1338-41-6) is 16 mg/L WAFA (ECHA) [Kl. score = 2]. -72-hr NOELR (no-observed-effect-loading-rate) to *Pseudokirschneriella subcapitata* for sorbitan stearate was 560 mg/L [WAF] (ECHA) [Kl. score = 1]. **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 0.32 mg/L WAF **$PNEC_{soil}$** -10 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Property: log Kow 5.19 - 5.89 BCF - 36 L/KG to 92 L/kg PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Glutaraldehyde	111-30-8	Tier 2	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment: The overall conclusion is that glutaraldehyde is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is readily biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to gluteraldehyde (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Sorbitan, mono-9-octadecenoate, (Z)	1338-43-8	Tier 1 (Qualitative Assessment/ PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that sorbitan monooleate polyoxyethylene derivative is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Ethoxylated oleic acid	9004-96-0	0.44	**Aquatic Toxicity** Acute Aquatic - Fish 96-hour - LC_{50} *Danio rerio* and *Cyprinus carpio* 1.2 mg/L Acute Aquatic - Invertebrate 48-hour EC_{50} *Daphnia magna* - 0.39 mg/L Acute Aquatic - Algae 72 hour EC_{50} *Desmodesmus subspicatus* - 1.4 mg/L (biomass) and 1.8 mg/L (growth rate) **Terrestrial Toxicity** -OECD 207 NOEL - *Eisenia fetida* - >1,000 mg/kg dw **PNECwater -** 0.039 mg/L **PNECsoil -** 1 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium Chloride	7647-14-5	0.30	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 *Lepomis macrochirus* - 5,840 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 1,900 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr NOEC *Lemna* - 6,780 mg/L **Chronic Toxicity** Chronic Aquatic - Fish 33-day NOEC - *Pimephales promelas* - 232 mg/L Chronic Aquatic - Invertebrate 21-day NOEC - *Daphnia pulex* - 314 mg/L **Terrestrial Toxicity** -14-day LC50 *E. fetida* - 3296 mg/kg soil dw -10-week NOEC *E. fetida* - 3,507 mg/kg soil -7-day EC50 - red fescue grass - 500.8 mg/kg soil -12-hr LD50 - wild house sparrow - 3,000 - 3,500 mg/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Essential ions to biological systems. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium Tetraborate Decahydrate	1303-96-4	0.26	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 Fathead minnow 79.7 mg B/L Aquatic Invertebrate -96-hr LC50 *Legumia recta* (black sandshell mussel) 147 mg B/L -96-hr LC50 *Hyalella azteca* 64 mg B/L Aquatic Algae -72-hr EC50 *Pseudokirchneriella subcapitata* 52.4 mg B/L Chronic Aquatic - Fish -34-day NOEC *Danio rerio 1.8* mg B/L -32-day NOEC *Pimephales promelas* 11 mg B/L Chronic Aquatic - Invertebrate -14-day NOEC *Daphnia magna* - 2.4 mg B/L Chronic Aquatic - Algae -4-day NOEC *Pseudokirchneriella subcapitata* - 2.8 mg B/L **Terrestrial Toxicity** -Soil inverteretes - NOEC ranging from 5.2 mgB/kg dw to 315 mg B/kg **$PNEC_{water}$** - 0.94 mg/L (ANZECC Water Quality Guideline for 95% species protection for boron in freshwater) **$PNEC_{soil}$** -5.7 mg/kg soil dry weight (derived for boron)	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Ethoxylated oleic acid	9004-96-0	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that sorbitan monooleate polyoxyethylene derivative is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Sodium Chloride	7647-14-5	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017). In Technical report number 14, releases to surface waters were found to have limited long-term environmetnal effects because sodium chloride is ubiquitous and present in most water, soil, and sediment. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium Tetraborate Decahydrate	1303-96-4	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that sodium tetraborate decahydrate is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Ammonium Chloride	12125-02-9	0.26	**Aquatic Toxicity** Acute toxicity - Fish -Ranbow trout - 42.91 mg/L ammonium chloride, -Mountain whitefish (Prosopium williamsoni): LC50 (96h) 46.27 mg/L for ammonium chloride; Acute toxicity - Invertebrates - *Daphnia magna* 136.6 mg/L - EC_{20} *Daphnia magna* 47 mg/L Acute Acute - Algae -EC_{50} *Chlorella vulgaris* 1300 mg/L Chronic toxicity - Fish -Lepomis macrochirus EC20 = 4.28 mg/L ammonium chloride. **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 0.25 mg/L **$PNEC_{soil}$** -not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties - Substance is inorganic, dissociates completely. PBT Assessment: Not applicable	Environmental Fate Properties: Not expected to bioacumulate because inorganic PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Gelatins	9000-70-8	0.23	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradeable PBT Assessment: Does not meet screening criteria for persistance.	Environmental Fate Properties: Naturally occurring in animal products and are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Calcium Chloride	10043-52-4	0.15	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 - *Pimephales promelas* - 4,630 mg/L -96-hr LC50 - *Lepomis macrochirus* (two studies) - 9,500-11,300 mg/L -96-hr LC50 - *Gambusia affinis* - 13,400 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* (three studies) - 1,062 mg/L and 2,770 mg/L -48-hr EC50 - *Ceriodaphnia dubia* - 1,830 mg/L Acute Aquatic - Algae -72-hr EC50 *Pseudokirchneriella subapitata* - 2,900 mg/L Chronic Aquatic - Invertebrate -21-day EC50 *Daphnia* - 610 mg/L **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 11 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assesment: Human Health Hazard - low concern (moderate eye irritation) Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Essential ions to biological systems. Neither calcium chloride or its dissociated ions are expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Vinylidene chloride/methylacrylate copolymer	25038-72-6	0.072	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assesment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: No data available PBT Assessment: Not applicable	Environmental Fate Properties: Not expected to bioaccumulate due to large molecular weight of substance PBT Assessment: Not applicable

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Ammonium Chloride	12125-02-9	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that ammonium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is dissociates completely, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA
	Gelatins	9000-70-8	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in an IMAP Tier 1 assessment and considers this chemical of low concern to the environment PBT Assessment: The overall conclusion is that gelatins is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted.	NA
	Calcium Chloride	10043-52-4	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that calcium chloride is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (eye irritant). The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. No additional management required, Tier 1 screening satisfied.	NA
	Vinylidene chloride/methylacrylate copolymer	25038-72-6	Tier 1 (NICNAS)	NICNAS: Determined to be low concern polymer under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) targeted tier I approach. (AICIS, 2021). An IMAP Tier 1 assessment completed by NICNAS considers it a polyme of loc concern for both human health and the environment. Management: No additional management required, Tier 1 screening satisfied.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	but-2-enedioic acid (Fumaric Acid)	110-17-8	0.061	**Aquatic Toxicity** Acute Aquatic - Fish -96-h LC_{50} *Danio rerio* - >100 mg/L Acute Aquatic - Invertebrate -48-h EC_{50} *Daphnia magna* - >100 mg/L Acute Aquatic - Algae -72-h EC_{50} *Pseudokirchneriella subcapitata* - >100 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 1 mg/L **$PNEC_{soil}$** - 0.0115 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Bioaccumulation of but-2-enedoic acid is not expected to occur based on its log K_{ow} value of -4.02. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.080	**Aquatic Toxicity:** Acute Aquatic - Fish -96 hour LC_{50} - *Salmo gairdneri* 3.2 mg/L Acute Aquatic - Invertebrates 48-hour EC_{50} - *Dapnia magna* - 0.09 mg/L Acute Aquatic - Algae -72 hour EC_{50} *Pseudokirchneriella subcapitata* 0.062 mg/L Chronic Aquatic - Fish 34 day NOEC - *Pimephales promelas* - 0.032 mg/L Chroni Aquatic - Invertebrates 21 day NOEC - *Daphnia magna* - 0.0068 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.00062 mg/L **$PNEC_{soil}$** - 25.6 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Moderate concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: log Kow = 3.15 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Alcohols, C12-14-secondary, ethoxylated	84133-50-6	0.062	**Aquatic Toxicity** -NOEC = freshwater fish: 2 species - 720 to 1,500 mg/L -NOEC = freshwater crustaceans: 2 species - 590 to 860 mg/L -NOEC - Freshwater rotifers Brachionus calyciflorus - 1,300 mg/L -NOEC - Freshwater algae, diatoms and blue-green algae: 6 species - 200 to 8,700 mg/L **Chronic Aquatic - Invertebrate** -No data available **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 0.14 mg/L (ANZECC Water Quality Guideline for alcohol ethoxyates) **$PNEC_{soil}$** -5.6 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Expected to have a low potential for bioaccumulation and a moderate potential for adsorption to soil and sedminet. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Non-crystalline Silica (impurity)	7631-86-9	0.036	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Hazard: Inhalation: silicosis and lung cancer in humans. Oral/dermal: low concern. Ecological Hazard: Low concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: inorganic complex not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	but-2-enedioic acid (Fumaric Acid)	110-17-8	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that but-2-enedioic acid is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Dicoco dimethyl quaternary ammonium chloride	61789-77-3		PBT Assessment: The overall conclusion is that Dicoco dimethyl quaternary ammonium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	
	Alcohols, C12-14-secondary, ethoxylated	84133-50-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Alcohols, C12 to C14 secondary, ethoxylated are not PBT substances. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Non-crystalline Silica (impurity)	7631-86-9	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Crystalline silica, quartz is not a PBT substance. Qualitative Assessment indicated hazardous to human health by the inhalation pathway; not hazardous by the oral/dermal route. Percent volume in mixture is less than 0.1-percent of the mixture. Therefore, according to the GHS criteria the concentration of the substance in the mixture would not meet the criteria of carcinogenicity. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore a Tier 2 Assessment is not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	2,2"-oxydiethanol - impurity (Diethylene glycol)	111-46-6	0.0158	**Aquatic Toxicity** Acute Aquatic - Fish -96-h LC_{50} *Pimephales promelas* - 75,200 mg/L -96-h LC_{50} *Oncorhynchus mykiss* - 66,000 Acute Aquatic - Invertebrate -24-h EC_{50} *Daphnia magna* ->10,000 mg/L -48-hr EC_{50} *Daphnia magna* - 65,980 mg/L -48-hr EC_{50} *Daphnia magna* - 62,630 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L (for ethylene glycol) Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L (for ethylene glycol) -21 day - *Daphnia magna* - > 15,000 mg/L (for triethylene glycol) Chronic Aquatic - Algae -8-day TGK to algae *Scenedesmus quadricauda* 2,700 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 27 mg/L **$PNEC_{soil}$** - 0.36 mg/kg dry weight soil	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow = -1.98 (calculated) PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	2-Propenamid (impurity)	79-06-1	0.0174	**Aquatic Toxicity** Acute Aquatic - Fish -LC_{50} Rainbow Trout, *Onchorhyncus mykiss* , 180 mg/L Acute Aquatic - Invertebrate -48 hour EC50 - *Daphnia Magna* - 60 mg/L Acute Aquatic - Algae -72 hour EC50 - *Pseudokirchneriella subcapitata* - 33 mg/L Chronic Aquatic - Fish -28 day - NOEC *Cyprinus carpio* - 5 mg/L **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 0.05 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: log Kow of -0.67 PBT Assessment: Does not meet the screening criteria for bioaccumulation
	Propan-2-ol	67-63-0	0.0158	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimpephales promelas* - 9,640 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} *Daphnia magna* >10,000 mg/L **Chronic Aquatic - Invertebrate** -16 day NOEC *Daphnia magna* 141 mg/L -21 day NOEC *Daphnia magna* 30 mg/L -7-day NOEC *Scenedesmus quadricauda* is 1,800 mg/L **Terrestrial Toxicity** -EC_{50} lettuce seed germination test - 2,100 mg/L **$PNEC_{water}$** - 0.3 mg/L **$PNEC_{soil}$** - 0.014 mg/kg	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation of isopropanol is not expected to occur based on its log K_{ow} value of 0.05. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	2,2"-oxydiethanol - impurity (Diethylene glycol)	111-46-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Diethylene glycol is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	2-Propenamid (impurity)	79-06-1	Tier 1 (Qualitative/PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that 2-propenamid (impurity) is not a PBT substance. Qualitative Assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA
	Propan-2-ol	67-63-0	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Propan-2-ol is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
May-21	Potassium chloride	7447-40-7	0.0047	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimpephelas promelas* - 880 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* 660 mg/L -48-hr EC_{50} *Ceriodaphnia dubia* - 630 mg/L Acute Aquatic - Algae and other plants -72-hr EC_{50} *Scenedesmus subspicatus* - >100 mg/L **Chronic Aquatic - Invertebrate** -7-day NOEC in a fathead minnow is 500 mg/L **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 1 mg/L (algae) **$PNEC_{soil}$** -not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Will dissociate to potassium and chloride ions which are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Diutan Gum	595585-15-2	0.0032	**Aquatic Toxicity** Acute Aquatic-Fish -96-h LC_{50} *Oncorhynchus mykiss* - 100 mg/L Acute Aquatic- Invertebrate -48-h EC_{50} Daphnid species - 100 mg/L Acute Aquatic - Algae -72 h EC50 Freshwater algae - >100 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 1 mg/L **$PNEC_{soil}$** - 0.01 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation of duitan gum is not expected to occur based on its log K_{ow} value of 3.56. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Magnesium Silicate Hydrate (talc)	14807-96-6	0.0024	**Aquatic Toxicity** Acute Aquatic -96-h LC_{50} Unnamed fish species - 89,581 mg/L (QSAR) -48-h LC_{50} Daphnid species - 36,812 mg/L (QSAR) -96 h LC50 Freshwater algae - 7,203 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 72 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Biodegradability is not relevant because inorganic substance. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation not expected to occur based on its log K_{ow} value of -9.4. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
May-21	Potassium chloride	7447-40-7	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Potassium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Diutan Gum	595585-15-2	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that duitan gum is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Magnesium Silicate Hydrate (talc)	14807-96-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that magnesium silicate is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Crystalline silica, quartz	14808-60-7	100	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Hazard: Inhalation: silicosis and lung cancer in humans. Oral/dermal: low concern. Ecological Hazard: Low concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: inorganic complex not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Choline Chloride (2-hydroxy-N,N,N-trimethylethanaminium chloride)	67-48-1	100	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oryzias latipes* - >100 mg/L (nominal and measured) -96-hr LC_{50} *Leuciscus idus* - >10,000 mg/L (78% solution of choline chloride) Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 349 mg/L (nominal and measured) -48-hr EC_{50} *Daphnia magna* - >500 mg/L (78% solution of choline chloride) Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - >1,000 (nominal and measured) Chronic Aquatic - Invertebrate -21-day *Daphnia magna* reproduction test NOEC 30.2 mg/L (nominal and measured) Chronic Aquatic - Algae and other aquatic plants -72-hr *Pseudokirchneriella subcapitata* study NOEC 30.2 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.3 mg/L **$PNEC_{soil}$** - 0.007 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Experimental log Kow is -3.77 PBT Assessment: Does not meet the criteria for bioaccumulation.
	Guar gum	9000-30-0	100	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 218 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 42 mg/L -96-hr LC_{50} *Daphnia magna* - <6.2 mg/L Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.006 mg/L (Acute *Daphnia*) **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern to fish, moderate acute toxicity to invertebrates PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Crystalline silica, quartz	14808-60-7	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Crystalline silica, quartz is not a PBT substance. Qualitative Assessment indicated hazardous to human health by the inhalation pathway; not hazardous by the oral/dermal route. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore a Tier 2 Assessment is not warranted.	NA
	Choline Chloride (2-hydroxy-N,N,N-trimethylethanaminium chloride)	67-48-1	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) PBT Assessment: The overall conclusion is that choline chloride is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. This chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Guar gum	9000-30-0	Tier 1 (NICNAS/ PBT/ Exposure Assessment)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - unlikely to cause harm to workers Environment -Potentially harmful to the environment in the event of transport spill NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017) Qualitative assessment indicated low concern to human health. PBT Assessment - The overall conclusion is that guar gum is not a PBT substance. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Ulexite	1319-33-1	10.00	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 Fathead minnow 79.7 mg B/L Aquatic Invertebrate -48-hr Freshwater invertebrates 64 - > 544 mg B/L Aquatic Algae -72-hr EC50 *Pseudokirchneriella subcapitata* 52.4 mg B/L Chronic Aquatic - Fish -4-day EC10 *Microp salmoides 36.8* mg B/L -long term NOEC-LOEC *Pimephales promelas* 21.3 mg B/L -long term NOEC-LOEC Brachydanio rerio - 36 mg/L Chronic Aquatic - Invertebrate -NOEC *Daphnia magna* - 13.9 mg B/L -NOEC Hyalella azteca - 6.3 mg B/L Chronic Aquatic - Algae and aquatic plants -NOEC *Brachionus calyciflorus* 24.6 mg B/L -NOEC *Lampsilis siliquoidea* - 30 mg B/L **Terrestrial Toxicity** -NOEC ranging from 7.2 mgB/kg dw to 86.7 mg B/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Envrionmental Fate Property: Naturally occuring mineral; not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Ethylene glycol	107-21-1	10.00	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimephales promelas* - >72,860 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 22,810 mg/L and 24,591 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - >100 mg/L, 46,300 mg/L ($20^{o}C$), 51,000 mg/L ($24^{o}C$) -48-hr EC50 *Ceriodaphnia dubia-affinis* - 25,800 mg/L ($20^{o}C$), 10,000 mg/L ($24^{o}C$) Acute Aquatic - Algae and other aquatic plants -96-hr IC_{50} *Selenastrum capricornutum* - 10,940 mg/L -96-hr NOEC *Selenastrum capricornutum* - 10,000 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L Chronic Aquatic - Algae -72-hr NOEC *Pseudokirchneriella subcapitata* - >100 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 10 mg/L **$PNEC_{soil}$** - 0.13 mg/kg soil dry weight (equilibrium partitioning method)	Qualitative Assessment: Human Health Hazard - Repeated exposures may cause kidney toxicity Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: -Calculated log Kow is -1.36 -BCF in golden ide (*Leuciscus idus melanotus*) after 3 days exposure was 10 PBT Assessment: Does not meet the criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Ulexite	1319-33-1	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that ulexite is not a PBT substance. Qualitative assessment indicated low concern to human health. Management: No additional management required, Tier 1 screening satisfied.	NA
	Ethylene glycol	107-21-1	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that ethylene glycol is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., kidney toxicity). Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
	Diammonium peroxidisulphate	7727-54-0	10	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 76.3 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - 120 mg/L Acute Aquatic - Algae -72-hr EC_{10} *Phaedactylum tricornutum* - 320 mg/L Chronic Aquatic - Invertebrate -21-day NOEC *Daphnia magna* 20.8 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - 0.076 mgL **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Moderate concern (irigating to eyes, skin, and respiratory tract.) Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Inorganic salt that dissolves to respective cations and anions. PBT Assessment: Does not meet the screening criteria for bioaccumulation. Diammonium peroxidisulphate is not a PBT substance

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
	Diammonium peroxidisulphate	7727-54-0	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that sodium diammonium peroxodisulphate is not a PBT substance. Qualitative assessment indicated potential human hazard (e.g., skin, eye, and respiratory irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is dissociates completely, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Sodium hydroxide	1310-73-2	10	**Aquatic Toxicity** Acute Aquatic - Fish -24-hr LC50 *Carassius auratus* - 160 mg/L -48-hr LC50 *Leuciscus idus melanotus* - 189 mg/L -96-hr LC50 *Gambusia affinis* - 125 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Ceriodaphnia cf. dubia* - 40 mg/L -toxicity threshold of sodium hydroxide for Daphnia magna - 40 mg/L ot 240 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Property: Sodium hydroxide is not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Acrylamide, sodium acrylate copolymer	25085-02-3	10	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. Due to poor solubility and high molecular weight not expected to be bioavailable. Does not contain any reactive functional groups. **PNECwater -** not derived **PNECsoil -** not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance due to its very high molecular weight and poor water solubility.	Environmental Fate Property: Not readily biodegradable PBT Assessment: Does meet the screening criteria for persistence.	Environmental Fate Property: Very high molecular weight and poor water solubility PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy	31726-34-8	10	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Oncorhynchus mykiss* - 1,464 mg/L -96-hr LC_{50} *Pimephales promelas* - range from 1,580 mg/L - 2,137 mg/L -96 hr LC_{50} - *Lepomis machrochirus* - 1,490 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - range from - 881 mg/L - 2,650 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Pseudokirchneriella subcapitata* - 911 mg/L (biomass); 88 mg/L -72-hr EC_{50} *Selenastrum capricornutum* - 720 mg/L (biomass); 280 mg/L **Chronic Toxicity** Chronic Aquatic - Fish -21-day NOEC *Brachydanio rerio* - > 100 mg/L Chronic Aquatic - Invertebrate - 21-day NOEC *Daphnia magna* - 100 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 8.8 mg/L **$PNEC_{soil}$** - 0.9 mg/kg soil dry weight	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Harmful to aquatic life PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is 0.81 No bioconcentration studies PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt	129898-01-7	10.00	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Rianbow Trout - >1,000 mg/L -96-hr LC_{50} Zebra Fish - >1,000 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} *Daphnia* - 320 mg/L Acute Aquatic - Algae -72-hr EC_{50} - 130 mg/L **Terrestrial Toxicity** No terrestrial toxicity studies identified. **$PNEC_{water}$** - 0.13 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - Low toxicity concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Meets 150 day critierion for ultimate biodegradability. PBT Assessment: Meets the screening criteria for persistence	Environmental Fate Property: Not expected to bioaccumulate in the environment. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Sodium hydroxide	1310-73-2	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that sodium hydroxide is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA
	Acrylamide, sodium acrylate copolymer	25085-02-3	Tier 1 (NICNAS/PBT/Exposure Assessment)	NICNAS: Identified as chemical of low concern for human health in an IMAP Tier 1 assessment and considers these polymers of low concern to human health PBT Assessment: The overall conclusion is that acrylamide/sodium acrylate copolymer is not a PBT substance. Management: No additional management required, Tier 1 screening satisfied.	NA
	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy	31726-34-8	Tier 1 (Qualitative/PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt	129898-01-7	Tier 1 (Qualitative/PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that 2-propenoic acid, polymer with sodium phosphinate is not a PBT substance. Qualitative Assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is ultimately biodegradable, does not bioaccumulate, and does not meet the PBT criteria for toxicicty. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Glutaraldehyde	111-30-8	1.00	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Bluegill Sunfish - 13 mg/L -96-hr LC_{50} *Oncorhynchus mykiss* - 10 mg/L Acute Aquatic - Invertebrate -48-hr LC_{50} *Daphnia magna* - 14.87 mg/L and 14 mg/L Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Scenedesmus subspicatus* - 0.375 mg/L (biomass), 0.6 (growth rate), 0.025 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.92 mg/L (biomass), 0.61 (growth rate), 0.33 (NOEC) -72-hr EC_{50} *Scenedesmus subspicatus* - 0.61 mg/L (growth rate) Chronic Aquatic - Fish -97-day LOEC *Oncorhynchus mykiss* - 5 mg/L -97-day NOEC *Oncorhynchus mykiss* - 1.6 mg/L Chronic Aquatic - Invertebrate -21-day NOEC *Daphnia magna* - 5 mg/L **Terrestrial Toxicity** Earthworms -14-day LC50 - 500 mg/kg soil dry weight Soil microoganisms -28-day EC50 - 360 mg/kg soil dry weight - > 593 mg/kg soil dry weight -28-day EC10 - 1.5 mg/kg soil dry weight - 11.5 mg/kg soil dry weight Avian -single dose (oral gavage) LC50 Mallard duck - 206 mg/kg -5-day dietary NOEC - Mallard duck - >2,500 ppm Terrestrial Plants: -19-day EC_{50} - *Avena sativa* (oats) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate, dry matter, shoot length) -19-day EC_{50} . *Brassica napus* (rapeseed) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 500 (dry matter), 250 (shoot length) -19-day EC_{50} - *Vicia sativa* (vetch) - >1,000 mg/kg soil dry weight; NOEC - >1000 (emergence rate), 125 (dry matter), 125 (shoot length) **$PNEC_{water}$** - 0.0025 mg/L (Chronic algae) **$PNEC_{soil}$** -0.02 mg/kg soil dry weight (lChronic soil organisms)	Qualitative Assessment: Human Health Hazard - Corrosive; skin/respiratory sensitizer Ecological Hazard - Very toxic to aquatic life with long lasting effects. Moderatly toxic to birds on acute basis. PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Hydrochloric acid	7647-01-0	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Lepomis macrochirus* - pH 3.25-3.5 (20 mg/L) Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* - pH 4.92 (0.45 mg/L) Acute Aquatic - Algae and other aquatic plants -72-hr EC_{50} *Chlorella vulgaris* - pH 4.7 (growth rate) (0.73 m/L), pH 4.7 (0.364 mg/L) Chronic Aquatic -No chronic studies available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Corrosive; respiratory irritant Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely PBT Assessment: Not applicable.	Environmental Fate Property: Expected to not bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Glutaraldehyde	111-30-8	Tier 2	NICNAS Assessment (2018) Human Health - potentially harmful to public health in event of transport spill. - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment: The overall conclusion is that glutaraldehyde is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., skin irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is readily biodegradable and does not bioaccumulate. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to gluteraldehyde (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Hydrochloric acid	7647-01-0	Tier 1 (NICNAS/ Qualitative Assessment/ PBT)	NICNAS Assessment (2018) Human Health - unlikely to cause harm to public - potentially harmful to workers health in event of industrial incident Environment -Potentially harmful to the environment in the event of transport spill PBT Assessment - The overall conclusion is that hydrochloric acid is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (e.g., corrosive). Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted.	NA

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Sodium Tetraborate Decahydrate	1303-96-4	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 Fathead minnow 79.7 mg B/L Aquatic Invertebrate -96-hr LC50 *Legumia recta* (black sandshell mussel) 147 mg B/L -96-hr LC50 *Hyalella azteca* 64 mg B/L Aquatic Algae -72-hr EC50 *Pseudokirchneriella subcapitata* 52.4 mg B/L Chronic Aquatic - Fish -34-day NOEC *Danio rerio 1.8* mg B/L -32-day NOEC *Pimephales promelas* 11 mg B/L Chronic Aquatic - Invertebrate -14-day NOEC *Daphnia magna* - 2.4 mg B/L Chronic Aquatic - Algae -4-day NOEC *Pseudokirchneriella subcapitata* - 2.8 mg B/L **Terrestrial Toxicity** -Soil inverteretes - NOEC ranging from 5.2 mgB/kg dw to 315 mg B/kg **$PNEC_{water}$** - 0.94 mg/L (ANZECC Water Quality Guideline for 95% species protection for boron in freshwater) **$PNEC_{soil}$** -5.7 mg/kg soil dry weight (derived for boron)	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Expected to have a low potential for bioaccumulation PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Sodium Chloride	7647-14-5	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 *Lepomis macrochirus* - 5,840 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 1,900 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr NOEC *Lemna* - 6,780 mg/L **Chronic Toxicity** Chronic Aquatic - Fish 33-day NOEC - *Pimephales promelas* - 232 mg/L Chronic Aquatic - Invertebrate 21-day NOEC - *Daphnia pulex* - 314 mg/L **Terrestrial Toxicity** -14-day LC50 *E. fetida* - 3296 mg/kg soil dw -10-week NOEC *E. fetida* - 3,507 mg/kg soil -7-day EC50 - red fescue grass - 500.8 mg/kg soil -12-hr LD50 - wild house sparrow - 3,000 - 3,500 mg/kg **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Essential ions to biological systems. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Sodium Tetraborate Decahydrate	1303-96-4	Tier 1 (Qualitative Assessment/PBT Exposure Assessment)	PBT Assessment: The overall conclusion is that sodium tetraborate decahydrate is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical dissociates completely in aqueous media and persistence criteria is not applicable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Sodium Chloride	7647-14-5	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in National assessment of chemicals associated with coal seam gas extraction in Australia, Tech Report Number 11 (NICNAS, 2017). In Technical report number 14, releases to surface waters were found to have limited long-term environmetnal effects because sodium chloride is ubiquitous and present in most water, soil, and sediment. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA

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Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Ammonium sulfate	7783-20-2	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hour *Onchorhyncus mykiss, Salmo gairdneri* - LC50 - 53 mg/L -96-hour *Prosopium williamsoni* - LC50 - 57.2 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 169 mg/L -48-hr EC50 *Ceriodaphnia acanthina* - 121.7 mg/L Chronic Aquatic - Fish -30-day *Lepomis macrochirus* - EC10 5.29 mg/L Chronic Aquatic - Invertebrate -10-week EC10 *Hyallella azteca* - 3.12 mg/L Chronic Aquatic - Algae -18-day EC50 - *Chlorella vulgaris* - 2,700 mg/L -5-day EC50 - *Chlorella vulgaris* - 1,605 mg/L **Terrestrial Toxicity** No data were available **$PNEC_{water}$** - 0.312 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is -5.1 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer	38193-60-1	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 *Lepomis macrochirus* - 1,000 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 1,000 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr NOEC *Pseudokirchneriella subcapitata* - 2,000 mg/L Chronic Aquatic No data available. **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 10 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is -4.34 No bioconcentration studies PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Vinylidene chloride/methylacrylate copolymer	25038-72-6	0.1	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assesment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: No data available PBT Assessment: Not applicable	Environmental Fate Properties: Not expected to bioaccumulate due to large molecular weight of substance PBT Assessment: Not applicable
	Calcium Chloride	10043-52-4	1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 - *Pimephales promelas* - 4,630 mg/L -96-hr LC50 - *Lepomis macrochirus* (two studies) - 9,500-11,300 mg/L -96-hr LC50 - *Gambusia affinis* - 13,400 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* (three studies) - 1,062 mg/L and 2,770 mg/L -48-hr EC50 - *Ceriodaphnia dubia* - 1,830 mg/L Acute Aquatic - Algae -72-hr EC50 *Pseudokirchneriella subapitata* - 2,900 mg/L Chronic Aquatic - Invertebrate -21-day EC50 *Daphnia* - 610 mg/L **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 11 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assesment: Human Health Hazard - low concern (moderate eye irritation) Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Not applicable	Environmental Fate Properties: Essential ions to biological systems. Neither calcium chloride or its dissociated ions are expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Feb-22	Ammonium sulfate	7783-20-2	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that ammonium sulfate is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer	38193-60-1	Tier 1 (NICNAS/Qualitative/ PBT)	NICNAS: Determined to be low concern polymer under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) targeted tier I approach. (AICIS, 2021). An IMAP Tier 1 assessment completed by NICNAS considers it a polymer of low concern for both human health and the environment. PBT Assessment: The overall conclusion is that Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer is not a PBT substance. Qualitative assessment indicated low concern to human health and ecological receptors. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Vinylidene chloride/methylacrylate copolymer	25038-72-6	Tier 1 (NICNAS)	NICNAS: Determined to be low concern polymer under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) targeted tier I approach. (AICIS, 2021). An IMAP Tier 1 assessment completed by NICNAS considers it a polymer of low concern for both human health and the environment. Management: No additional management required, Tier 1 screening satisfied.	NA
	Calcium Chloride	10043-52-4	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that calcium chloride is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (eye irritant). The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. No additional management required, Tier 1 screening satisfied.	NA

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	but-2-enedioic acid (Fumaric Acid)	110-17-8	0.100	**Aquatic Toxicity** Acute Aquatic - Fish -96-h LC_{50} *Danio rerio* - >100 mg/L Acute Aquatic - Invertebrate -48-h EC_{50} *Daphnia magna* - >100 mg/L Acute Aquatic - Algae -72-h EC_{50} *Pseudokirchneriella subcapitata* - >100 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 1 mg/L **$PNEC_{soil}$** - 0.0115 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Bioaccumulation of but-2-enedoic acid is not expected to occur based on its log K_{ow} value of -4.02. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.100	**Aquatic Toxicity:** Acute Aquatic - Fish -96 hour LC_{50} - *Salmo gairdneri* 3.2 mg/L Acute Aquatic - Invertebrates 48-hour EC_{50} - *Dapnia magna* - 0.09 mg/L Acute Aquatic - Algae -72 hour EC_{50} *Pseudokirchneriella subcapitata* 0.062 mg/L Chronic Aquatic - Fish 34 day NOEC - *Pimephales promelas* - 0.032 mg/L Chronic Aquatic - Invertebrates 21 day NOEC - *Daphnia magna* - 0.0068 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.00068 mg/L **$PNEC_{soil}$** - 28.1 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Moderate concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: log Kow = 3.15 PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Gelatins	9000-70-8	0.10	No ecotoxicity data available. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inherently biodegradeable PBT Assessment: Does not meet screening criteria for persistance.	Environmental Fate Properties: Naturally occurring in animal products and are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Non-crystalline Silica (impurity)	7631-86-9	0.100	**Aquatic and Terrestrial Toxicity** -No studies are available. -Expected to be low concern for toxicity to aquatic organisms. **$PNEC_{water}$** - not derived **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Hazard: Inhalation: silicosis and lung cancer in humans. Oral/dermal: low concern. Ecological Hazard: Low concern PBT Assessment: Substance exhibits higher toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not relevant PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: inorganic complex not expected to bioaccumulate PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Feb-22	but-2-enedioic acid (Fumaric Acid)	110-17-8	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that but-2-enedioic acid is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Dicoco dimethyl quaternary ammonium chloride	61789-77-3	Tier 2	PBT Assessment: The overall conclusion is that Dicoco dimethyl quaternary ammonium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical. However, this chemical is readily biodegradable, does not bioaccumulate, and does not meet the PBT assessment criteria for toxicity. Additionally, the potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. Therefore, a Tier 2 assessment was not warranted.	
	Gelatins	9000-70-8	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Identified as chemical of low concern for human health in an IMAP Tier 1 assessment and considers this chemical of low concern to the environment PBT Assessment: The overall conclusion is that gelatins is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Non-crystalline Silica (impurity)	7631-86-9	Tier 1 (Qualitative Assessment/ PBT)	PBT Assessment: The overall conclusion is that Crystalline silica, quartz is not a PBT substance. Qualitative Assessment indicated hazardous to human health by the inhalation pathway; not hazardous by the oral/dermal route. Percent volume in mixture is less than 0.1-percent of the mixture. Therefore, according to the GHS criteria the concentration of the substance in the mixture would not meet the criteria of carcinogenicity. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. Therefore a Tier 2 Assessment is not warranted.	NA

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate	136793-29-8	0.10	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC50 *Lepomis macrochirus* - 1,000 mg/L Acute Aquatic - Invertebrate -48-hr EC50 *Daphnia magna* - 1,000 mg/L Acute Aquatic - Algae and other aquatic plants -96-hr NOEC *Pseudokirchneriella subcapitata* - 2,000 mg/L Chronic Aquatic No data available. **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 10 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Property: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: Log Kow is -4.34 No bioconcentration studies PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	2,2"-oxydiethanol - impurity (Diethylene glycol)	111-46-6	0.1000	**Aquatic Toxicity** Acute Aquatic - Fish -96-h LC_{50} *Pimephales promelas* - 75,200 mg/L -96-h LC_{50} *Oncorhynchus mykiss* - 66,000 Acute Aquatic - Invertebrate -24-h EC_{50} *Daphnia magna* ->10,000 mg/L -48-hr EC_{50} *Daphnia magna* - 65,980 mg/L -48-hr EC_{50} *Daphnia magna* - 62,630 mg/L Chronic Aquatic - Fish -7-day NOEC *Pimephales promelas* - 15,380 mg/L (for ethylene glycol) Chronic Aquatic - Invertebrate -7-day NOEC *Ceriodaphnia dubia* - 8,590 mg/L (for ethylene glycol) -21 day - *Daphnia magna* - > 15,000 mg/L (for triethylene glycol) Chronic Aquatic - Algae -8-day TGK to algae *Scenedesmus quadricauda* 2,700 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 27 mg/L **$PNEC_{soil}$** - 0.36 mg/kg dry weight soil	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Property: log Kow = -1.98 (calculated) PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Urea	57-13-6	0.1	**Aquatic Toxicity** Acute Aquatic - Fish -48-h LC_{50} *Golden orfe fish* - 10,000 mg/L -96-h EC_{50} *Tilapia mossambica* - > 20,000 mg/L -96-hr EC_{50} *Barilius barna* - >9,100 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} *Daphnia magna* - >10,000 mg/L -24-hr EC_{50} *Helisoma trivolvis* - 14,241 mg/L -24-hr EC50 *Biomphalaria havanensis* - 13,532 mg/L Chronic Aquatic - Fish -No data are available. Chronic Aquatic - Algae -192 hr - *Scenedesmus quadricauda* - 10,000 mg/L - 7-day - *Scenedesmus quadricauda* - 10,000 mg/L - 192 hr - *Microcystis aeruginosa* - 47 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.94 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation is not expected to occur based on its log K_{ow} value of -1.73. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Feb-22	Polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate	136793-29-8	Tier 1 (Qualitative/PBT)	PBT Assessment: The overall conclusion is that Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer is not a PBT substance. Qualitative assessment indicated low concern to human health and ecological receptors. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	2,2"-oxydiethanol - impurity (Diethylene glycol)	111-46-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Diethylene glycol is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Urea	57-13-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that urea is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Propan-2-ol	67-63-0	0.1	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimpephales promelas* - 9,640 mg/L Acute Aquatic - Invertebrate -24-hr EC_{50} *Daphnia magna* >10,000 mg/L Chronic Aquatic - Invertebrate -16 day NOEC *Daphnia magna* 141 mg/L -21 day NOEC *Daphnia magna* 30 mg/L -7-day NOEC *Scenedesmus quadricauda* is 1,800 mg/L **Terrestrial Toxicity** -EC_{50} lettuce seed germination test - 2,100 mg/L **$PNEC_{water}$** - 0.3 mg/L **$PNEC_{soil}$** - 0.014 mg/kg	Qualitative Assessment: Human Health Hazard -Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation of isopropanol is not expected to occur based on its log K_{ow} value of 0.05. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Magnesium Silicate Hydrate (talc)	14807-96-6	0.1000	**Aquatic Toxicity** Acute Aquatic -96-h LC_{50} Unnamed fish species - 89,581 mg/L (QSAR) -48-h LC_{50} Daphnid species - 36,812 mg/L (QSAR) -96 h LC50 Freshwater algae - 7,203 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 72 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Biodegradability is not relevant because inorganic substance. PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation not expected to occur based on its log K_{ow} value of -9.4. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Diutan	595585-15-2	0.1000	**Aquatic Toxicity** Acute Aquatic-Fish -96-h LC_{50} *Oncorhynchus mykiss* - 100 mg/L Acute Aquatic- Invertebrate -48-h EC_{50} Daphnid species - 100 mg/L Acute Aquatic - Algae -72 h EC50 Freshwater algae - >100 mg/L Chronic Aquatic - Fish No data available **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 1 mg/L **$PNEC_{soil}$** - 0.01 mg/kg	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Bioaccumulation of duitan gum is not expected to occur based on its log K_{ow} value of 3.56. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Potassium chloride	7447-40-7	0.1000	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} *Pimpephelas promelas* - 880 mg/L Acute Aquatic - Invertebrate -48-hr EC_{50} *Daphnia magna* 660 mg/L -48-hr EC_{50} *Ceriodaphnia dubia* - 630 mg/L Acute Aquatic - Algae and other plants -72-hr EC_{50} *Scenedesmus subspicatus* - >100 mg/L **Chronic Aquatic - Invertebrate** -7-day NOEC in a fathead minnow is 500 mg/L **Terrestrial Toxicity** -No data available. **$PNEC_{water}$** - 1 mg/L (algae) **$PNEC_{soil}$** -not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Will dissociate to potassium and chloride ions which are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Feb-22	Propan-2-ol	67-63-0	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that isopropanol is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Magnesium Silicate Hydrate (talc)	14807-96-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that magnesium silicate is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Diutan	595585-15-2	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that duitan gum is not a PBT substance. Qualitative assessment indicated low concern to human health The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	Potassium chloride	7447-40-7	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that Potassium chloride is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

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Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Sodium sulfate	7757-82-6	0.10	**Aquatic Toxicity** Acute Aquatic - Fish -96-hr LC_{50} Pimephales promelas 7,960 mg/L Acute Aquatic - Invertebrate -48-hr EC50 - *Daphnia magna* - 4,736 mg/L Chronic Aquatic - Invertebrate -7-day - $LOEC_{50}$ - *Ceriodapnia dubia* 1,329 mg/l **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 11 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Dissociates completely in aqueous media PBT Assessment: Does not meet the screening criteria for persistence	Environmental Fate Properties: Will dissociate to sodium and sulfate ions which are not expected to bioaccumulate. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	2-Propenamid (impurity)	79-06-1	0.0010	**Aquatic Toxicity** Acute Aquatic - Fish -LC_{50} Rainbow Trout, *Onchorhyncus mykiss* , 180 mg/L Acute Aquatic - Invertebrate -48 hour EC50 - *Daphnia Magna* - 60 mg/L Acute Aquatic - Algae -72 hour EC50 - *Pseudokirchneriella subcapitata* - 33 mg/L Chronic Aquatic - Fish -28 day - NOEC *Cyprinus carpio* - 5 mg/L **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 0.05 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Readily biodegradable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: log Kow of -0.67 PBT Assessment: Does not meet the screening criteria for bioaccumulation
	Tetrasodium ethylenediaminetetraacetate	64-02-8	0.0010	**Aquatic Toxicity** Acute Aquatic - Fish -LC_{50} > 100 mg/L for Na_4EDTA and sodium salts Acute Aquatic - Invertebrate -24-hr EC50 - *Daphnia magna* - 480 to 790 mg/L Chronic Aquatic - fish -NOEC - zebra fish - >26.8 mg/L H_4EDTA Chronic Aquatic - Invertebrate -21-day NOEC - *Daphnia Magna* - 22 mg/L Aquatic - Algae -Ecb50, ECr50 - *Pseudokirchneriella subcapitata* - >100 mg/L -NOEC - *Pseudokirchneriella subcapitata* - 48.4 mg/L **Terrestrial Toxicity** No data available **$PNEC_{water}$** - 22 mg/L **$PNEC_{soil}$** - not derived	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not expected to biodegrade PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: BCF of 1.1 - 1.8 in fish. PBT Assessment: Does not meet the screening criteria for bioaccumulation.

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Feb-22	Sodium sulfate	7757-82-6	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: The overall conclusion is that sodium sulfate is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA
	2-Propenamid (impurity)	79-06-1	Tier 1 (Qualitative Assessment/PBT/ Exposure Assessment)	PBT Assessment: The overall conclusion is that 2-propenamid (impurity) is not a PBT substance. Qualitative Assessment indicated low human health concern and carcinogenicity to animals. Percent volume in mixture is less than 0.1-percent of the mixture. Therefore, according to the GHS criteria the concentration of the substance in the mixture would not meet the criteria of carcinogenicity. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: Australia SafeWork Place and inGauge Occupational Safety Guidance will be used to minimise human health exposure. Therefore, a Tier 2 assessment was not warranted for human receptors.	NA
	Tetrasodium ethylenediaminetetraacetate	64-02-8	Tier 1 (Qualitative Assessment/PBT)	PBT Assessment: While the OECD tests for tetrasodium ethylenediaminetetraacetate indicate that the criteria for persistance is satisified, it is believed to be ultimately biodegradable under environmental conditions. The overall conclusion is that tetrasodium ethylenediaminetetraacetate is not a PBT substance. Qualitative assessment indicated low concern to human health. The estimated injected concentration did not exceed the ecotoxicity values or PNECs for this chemical. Therefore, a Tier 2 assessment was not warranted. Management: No additional management required, Tier 1 screening satisfied.	NA

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Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Dimethyl siloxanes and silicones	63148-62-9	0.001	**Aquatic Toxicity** Acute Aquatic - Fish -96 hr - LC_{50} - 1.17 mg/L -96 hr - LC50 - 0.963-2.5203 mg/L Chronic Aquatic- Fish -7 day LC50 *Ictalurus punctatus* - 3.16 mg/L **Terrestrial Toxicity** Chronic terrestrial -14-day NOEC Earthworms - 124 mg/kg bw/day -28-day - NOEC - *Folsomia candida* - 230 mg/kg bw/day -28- day NOEC soil microflora - > 1,000 mg/kg bw /day **$PNEC_{water}$** - 0.0632 mg/L **$PNEC_{soil}$** - 23 mg/kg bw/day	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not readily biodegradable PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: No evidence of bioaccumulation. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Siloxanes and silicones, dimethyl, reaction products with silica	67762-90-7	0.001	**Aquatic Toxicity** Acute Aquatic - Fish -96 hr - LC_{50} - 1.17 mg/L -96 hr - LC50 - 0.963-2.5203 mg/L Chronic Aquatic- Fish -7 day LC50 *Ictalurus punctatus* - 3.16 mg/L **Terrestrial Toxicity** Chronic terrestrial -14-day NOEC Earthworms - 124 mg/kg bw/day -28-day - NOEC - *Folsomia candida* - 230 mg/kg bw/day -28- day NOEC soil microflora - > 1,000 mg/kg bw /day **$PNEC_{water}$** - 0.0632 mg/L **$PNEC_{soil}$** - 23 mg/kg bw/day	Qualitative Assessment: Human Health Hazard - Low concern Ecological Hazard - Low concern PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Not readily biodegradable PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: No evidence of bioaccumulation. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Octamethylcyclotetrasiloxane	556-67-2	0.001	**Aquatic Toxicity** Acute Aquatic - Fish -96 hr LC_{50} *Oncorhynchus mykiss* > 0.022 mg/L Acute Aquatic - Invertebrate -48-hr NOEC/EC50 - *Daphnia magna* - >0.015 mg/L Acute Aquatic - Algae -96 hr LC50 - *Pseudokirchneriella subcapitata* - > 0.022 mg/L Chronic Aquatic - fish -93-day NOAEC - *Oncorhynchus mykiss* - ≥0.004 mg/L Chronic Aquatic - Invertebrate -21-day NOEC - *Daphnia Magna* - 0.0079 mg/L **Terrestrial Toxicity** No data available. **$PNEC_{water}$** - 0.0004 mg/L **$PNEC_{soil}$** - 10 mg/kg/dw	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance. However, classification is uncertain, refer to dossier.	Environmental Fate Properties: Not readibly biodegrade PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: measured BCF greater than 2000 L/kg PBT Assessment: Does meet the screening criteria for bioaccumulation.
	Decamethyl cyclopentasiloxane	541-02-6	0.001	**Aquatic Toxicity** Acute Aquatic - Fish -96 hr LC_{50} *Oncorhynchus mykiss* > 0.016 mg/L Acute Aquatic - Invertebrate -48-hr EC50 - *Daphnia magna* - >0.0029 mg/L Acute Aquatic - Algae -96 hr NOEC- *Pseudokirchneriella subcapitata* - > 0.016 mg/L Chronic Aquatic - fish -90-day NOAEC - *Oncorhynchus mykiss* - ≥ 0.014 mg/L Chronic Aquatic - Invertebrate -21-day NOEC - *Daphnia Magna* - 0.015 mg/L **Terrestrial Toxicity** -28 day and 56-day - NOEC *Eisenia andrei* (earthworms) - > 4,074 mg/kg/bw **$PNEC_{water}$** - 0.0004 mg/L **$PNEC_{soil}$** - 10 mg/kg/dw	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance. However, classification is uncertain, refer to dossier.	Environmental Fate Properties: Not readibly biodegrade PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: measured BCF greater than 2000 L/kg PBT Assessment: Does meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Dimethyl siloxanes and silicones	63148-62-9	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Determined to be low concern polymer under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) targeted tier I approach and concluded that it poses no unreasonable risk to human health and the environment. (AICIS, 2021). PBT Assessment: The overall conclusion is that dimethyl siloxanes and silicones is not a PBT substance. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA
	Siloxanes and silicones, dimethyl, reaction products with silica	67762-90-7	Tier 1 (NICNAS/Qualitative Assessment/PBT)	NICNAS: Determined to be low concern polymer under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) targeted tier I approach. (AICIS, 2021). PBT Assessment: The overall conclusion is that siloxanes and silicones, dimethyl, reaction products with silica is not a PBT substance. Qualitative assessment indicated low concern to human health Management: No additional management required, Tier 1 screening satisfied.	NA
	Octamethylcyclotetrasiloxane	556-67-2	Tier 2	PBT Assessment: The overall conclusion is that octamethylcyclotetrasiloxane is a PBT substance (with uncertainty). Qualitative Assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is not readily biodegradable and it does have potential to bioaccumulate. The potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. There is low concern to human health; therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to octamethylcyclotetrasiloxane (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Decamethyl cyclopentasiloxane	541-02-6	Tier 2	PBT Assessment: The overall conclusion is that Decamethyl cyclopentasiloxane is not a PBT substance. Qualitative Assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is not readily biodegradable and it does not bioaccumulate. The potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. There is low concern to human health; therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to decamethyl cyclopentasiloxane (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Concentration in Injected Fluid (mg/L)	Ecotoxicity	Toxicity	Biodegradation	Bioaccummulative
Feb-22	Copper(II) sulfate	7758-98-7	0.001	**Aquatic Toxicity** Acute Aquatic -toxicity data for Australian species range from 0.040 to 21 mg/L (for copper) Chronic Aquatic - fish -7-day LC50 - ranged from 0.0026 mg/L (*Ptylocheilus oregonenis*) to 0.131 mg/L (*Pimephales promelas*) (for copper) Chronic Aquatic - Invertebrate -NOEC - *D. pulex and G. pulex* - 0.0017 mg/L (for copper) -10 to 14-day NOEC - *Hyalella azteca* - 0.00121 mg/L (for copper) -14 day LC50 - *Flumicola virens* 0.00164 mg/L (for copper) Chronic Aquatic -Insects -10-day LC50 - *Tanytarsus dissimilis* - 0.0022 mg/L (for copper) -10 to 20-day LC50 *Chironomus tentans* - 0.011 mg/L (for copper) **Terrestrial Toxicity** -NOECs/EC10s vary between 8.4 mg/kg (*Eisenia andrei*) and 2,402 mg/kg (maize respiration) (for copper) **$PNEC_{water}$** - 0.0014 mg/L (ANZG water quality guideline for for copper at 95% species protection) **$PNEC_{soil}$** - 0.0001 mg/kg/dw	Qualitative Assessment: Human Health Hazard - Moderate concern (i.e., eye irritant) Ecological Hazard - Very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance.	Environmental Fate Properties: Inorganic substance; biodegradation not applicable PBT Assessment: Does not meet the screening criteria for persistence.	Environmental Fate Properties: Copper is an essential nutrient, therefore bioaccumulation is not relevant. Does not biomagnifiy in aquatic or terrestrial ecosystems. PBT Assessment: Does not meet the screening criteria for bioaccumulation.
	Dodecamethylcyclohexasiloxane	540-97-6	0.001	**Aquatic Toxicity** Acute Aquatic - Fish -96 hr LC_{50} *Oncorhynchus mykiss* > 0.016 mg/L (for Decamethylcyclopentasiloxane) Acute Aquatic - Invertebrate -48-hr NOEC/EC50 - *Daphnia magna* - >0.0029 mg/L (for Decamethylcyclopentasiloxane) Acute Aquatic - Algae -96 hr - *Pseudokirchneriella subcapitata* - > 0.016 mg/L Chronic Aquatic - fish -90-day NOAEC - *Oncorhynchus mykiss* - ≥ 0.014 mg/L Chronic Aquatic - Invertebrate -21-day NOEC - *Daphnia Magna* - 0.015 mg/L **Terrestrial Toxicity** -28 day and 56-day - NOEC *Eisenia andrei* (earthworms) - > 4,074 mg/kg/bw **$PNEC_{water}$** - 0.0004 mg/L **$PNEC_{soil}$** - 10 mg/kg/dw	Qualitative Assessment: Human Health Hazard - low concern Ecological Hazard - very toxic to aquatic life with long lasting effects. PBT Assessment: Substance exhibits lower toxicity than that established by regulatory guidance. However, classification is uncertain, refer to dossier.	Environmental Fate Properties: Not readibly biodegrade PBT Assessment: Meets the screening criteria for persistence.	Environmental Fate Properties: log Kow of 6.98 PBT Assessment: Does not meet the screening criteria for bioaccumulation.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Stimulation Formulation Evaluation	Chemical Name	CAS Number	Screening	Discussion	Outcome of Tier 2 Assessment
Feb-22	Copper(II) sulfate	7758-98-7	Tier 2	PBT Assessment: The overall conclusion is that copper (II) sulfate is not a PBT substance. Qualitative Assessment indicated potential hazard to human health (eye irritant). The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is an inorganic substance and does not bioaccumulate. The potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Australia WorkSafe and inGauge Occupational Health & Safety procedures will be used to minimise human health exposure. No additional management required, Tier 1 screening satisfied. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to copper (II)sulfate (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.
	Dodecamethylcyclohexasiloxane	540-97-6	Tier 2	PBT Assessment: The overall conclusion is that Dodecamethylcyclohexasiloxane is not a PBT substance. Qualitative Assessment indicated low concern to human health The estimated injected concentration did exceed the ecotoxicity values or PNECs for this chemical and does meet the screening criteria for toxicity. This chemical is not readily biodegradable and it does not bioaccumulate. The potential exposure to aquatic receptors is considered incomplete (refer to text). Therefore, a Tier 2 assessment was not warranted for aquatic receptors. Management: Implementation of Constraints Protocol in EMP will be required to prevent accidental discharge/release. There is low concern to human health; therefore, a Tier 2 assessment was not warranted for human receptors. Chemicals with a high ecotoxicity hazard assessment have a potential avian wildlife exposure to chemicals stored in treatment tanks. Therefore a Tier 2 assessment was conducted for avian receptors.	A quantitative risk characterisation was used to assess the risk to avian receptors from potential exposure to dodecamethylcyclohexasiloxane (Appendix F). There were no unacceptable potential risks to avian receptors as a result of ingestion of waters stored in treatment tanks.

Table 1
Evaluation of Compiled List of Chemicals
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement- Chemical Risk Assessment

Table Notes:
°C = degrees Celsius
µg/L = microgram per litre
ANZECC = Australian and New Zealand Environment Conservation Council
Ca:Mg = calcium:magnesium
CaCO3 = calcium carbonate
CAS = Chemical Abstract Service
CFT = Chemical Fracture Tracer
dw = dry weight
EC_0 = The concentration of a substance that is estimated to be lethal to 0% of the test organisms
EC_{50} = effects concentration of half the maximal response
ECHA = European Chemicals Agency
EG = ethylene glycol
EMP = Environmental Management Plan
GFT = Gas Fracture Tracer
HCO3- = bicarbonate
IMAP = Inventory Multi-tiered Assessment and Prioritisation
kg/L = kilogram per litre
Kow = n-octanol-water partition coefficient
L = litre
LC_{50} = lethal concentration of 50 percent of population
LOEC = lowest observed effects concentration
mg/kg = milligram per kilogram
mg/L = milligrams per litre
Na+ = Sodium ion
NA = not applicable
NICNAS = National Industrial Chemicals Notification and Assessment Scheme
NOEC = no observed effect concentration
NOELR = no observed effect loading rate
PBT = persistence, bioaccumulative, toxic
PEG - polyethylene glycol
PNEC = predicted no effect concentration
TGK = toxicity threshold (growth inhibition)
WAF = Water Accommodated Fraction Analysis
Additional NICNAS che
Silica dioxide
Sodium Chloride
Tributyl tetradecyl phosphonium chloride
UVCB = unknown or variable composition, complex reaction products or biological materials

Australian and New Zealand Environment and Conservation Council and Agriculture and Resource Management Council of Australia and New Zealand (ANZECC & ARMCANZ). (2000). Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Canberra, ACT: Author.

NICNAS 2017, Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

NICNAS 2018, Human health Tier II assessment, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

Organisation for Economic Co-operation and Development (OECD). (1992). Test No. 301: Ready Biodegradability. (Biodégradabilité Facile.) Paris: OECD Publishing.

Soucek, D.J. (2007). Comparison of hardness and chloride regulated acute effects of sodium sulfate on two freshwater crustaceans. Environ. Toxicol. Chem. 26: 773-779.

Australian Industrial Chemicals Introduction Scheme. 2021. Chemical Information Database. Available online at: https://www.industrialchemicals.gov.au/chemical-information/search-assessments

Appendix A Compiled List of Chemicals

Appendix A.1 Compiled List of March 2020 Chemicals

APPENDIX A

CHEMICAL SUMMARY LIST		
Chemical Name	**CAS Number**	**Max Concentration (mg/L)**
Choline Chloride	67-48-1	1096
Guar gum	9000-30-0	667
Hydrochloric acid	7647-01-0	474
Alcohols, C6-12, ethoxylated propoxylated	68937-66-6	199
Ethylene glycol	107-21-1	166
Ulexite	1319-33-1	209
Triethanol amine	102-71-6	150
Sodium Chloride	7647-14-5	249
Sodium polyacrylate	9003-04-7	126
Sodium hydroxide	1310-73-2	126
Alcohols, C10-16, ethoxylated propoxylated	69227-22-1	71
Acetic acid	64-19-7	66
Diethanolamine	111-42-2	65
Tributyl tetradecyl phosphonium chloride	81741-28-8	28
Acrylamide acrylate copolymer	9003-6-9	22
Sodium bisulfite	7681-38-1	47
Chlorous acid, sodium salt	7758-19-2	46
Disodium octaborate tetrahydrate	12008-41-2	25
Cinnamaldehyde	104-55-2	14
Polyethylene glycol	25322-68-3	16
Diethylene glycol	111-46-6	14
Crystalline silica, quartz	14808-60-7	25
Methanol	67-56-1	4
Sodium persulfate	7775-27-1	8
Amine oxides, cocoalkyldimethyl	61788-90-7	3
Citric acid	77-92-9	4
Benzaldehyde	100-52-7	2
Ethanol	64-17-5	1
Hydrotreated light petroleum distillate	64742-47-8	1
Fatty acids, tall-oil, ethoxylated	61791-00-2	1
Amides, tall-oil fatty, N,N- bis(hydroxyethyl)	68155-20-4	1
Butyl alcohol	71-36-3	1
Alcohols, C12-15, ethoxylated	68131-39-5	1
Alcohols, C12-16, ethoxylated	68551-12-2	1

Sodium iodide	7681-82-5	1
Acrylonitrile	107-13-1	0.1
Sodium Sulfate	7757-82-6	0.01
Glutaraldehyde	111-30-8	0.001
Acrylamide, sodium acrylate polymer	25987-30-8	143
Ethoxylated branched C13 alcohol	68439-54-3	10
Sobitan, mono-9-octadecenoate, (Z)	1338-43-8	13
Sodium diacetate	126-96-5	13
Sorbitan monooleate polyoxyethylene derivative	9005-65-6	13
Potassium chloride	7447-40-7	8.272
1,4-Dioxane-2,5-dione, 3,6- dimethyl-, (3R,6R)-, polymer with rel-(3R,6S)-3,6-dimethyl- 1,4- dioxane-2,5-dione and (3S,6S)- 3,6-dimethyl-1,4-dioxane-2,5- dione	9051-89-2	2.1804
Cocobetaine	61789-40-0	2.62
Sodium perborate tetrahydrate	10486-00-7	1.02
Sodium thiosulfate	7772-98-7	0.94
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	0
Hydroxylpropyl guar	39421-75-5	1.35
Glycerine	56-81-5	0.43
Polypropylene glycol	25322-69-4	0.353
Sodium Sulfite	7757-83-7	0.0043
Silica dioxide	112926-00-8	0.002
Sodium carbonate	497-19-8	0.002
Fatty acids, C8-C16, ethylhexyl ester	135800-37-2	6.31
Sodium bicarbonate	144-55-8	1.93
Iron gluconate	299-29-6	2.5
Aldol	107-89-1	1.29
Propylene glycol n-propyl ether	1569-01-3	1
Bismuth Oxide	1304-76-3	0.09
Crontonaldehyde	123-73-9	0.12
2-Ethyl hexanol	104-76-7	0.07
Acetaldehyde	75-07-0	0.07

Appendix A.2 Compiled List of May 2021 Chemicals

Schlumberger

Client:	Imperial Energy
Well:	Unknown
Basin/Field:	
State:	
County/Parish:	
Case:	
Disclosure Type:	Pre-Job
Well Completed:	
Date Prepared:	3/10/2021
Report ID:	RPT-1265

Fluid Name & Volume	Additive	Additive Description	Concentration	Volume
WF100:YF120FlexD:HVFR 1,109,400 gal	B499	Natural Corrosion Inhibitor B499	0.2 lb/mGal	240.0 lbm
	F112	Surfactant	1.8 Gal/mGal	2,035.8 gal
	H015	Acid	2.7 Gal/mGal	3,000.0 gal
	J218	Breaker J218	0.5 lb/mGal	544.5 lbm
	J475	Breaker J475	0.7 lb/mGal	771.6 lbm
	J580	Gel J580	13.9 lb/mGal	15,432.0 lbm
	J604 †	Crosslinker J604	0.7 Gal/mGal	771.6 gal
	J693	HV Friction Reducer J693	2.0 Gal/mGal	2,219.9 gal
	L065	Scale Inhibitor	0.9 Gal/mGal	1,017.9 gal
	L071	Clay Control Agent	1.8 Gal/mGal	2,035.8 gal
	M300	Myacide GA 25	0.5 Gal/mGal	509.0 gal
	S100	100 Mesh Sand	varied concentrations	131,000.0 lbm
	S521-4070-NRT	CARBOPROP® NRT S521-4070-NRT	varied concentrations	400,000.0 lbm
	S521-4070	Propping Agent	varied concentrations	869,000.0 lbm
	U028	Activator	0.5 Gal/mGal	514.4 gal

† Proprietary Technology

The total volume listed in the tables above represents the summation of water and additives. Water is supplied by client.

CAS Number	Chemical Name	Mass Fraction	Mass	Volume	Volume Fraction
-	Water (Including Mix Water Supplied by Client)*	~ 86 %	9,207,483.6	1,102,849.50	~ 87 %
66402-68-4	Ceramic materials and wares, chemicals	~ 12 %	1,269,000.0	152,059.70	~ 12 %
14808-60-7	Quartz, Crystalline silica	~ 1 %	131,000.0	6,037.40	< 1 %
9000-30-0	Guar gum	< 1 %	15,393.4	1,844.50	< 1 %
67-48-1	2-hydroxy-N,N,N-trimethylethanaminium chloride	< 1 %	14,016.4	1,526.90	< 1 %
26100-47-0	Acrylamide/ammonium acrylate copolymer	< 0.1 %	6,388.7	732.6	< 0.1 %
107-21-1	Ethylene Glycol	< 0.1 %	3,945.0	371.3	< 0.1 %
7647-01-0	Hydrochloric acid	< 0.1 %	3,755.4	450	< 0.1 %
64742-47-8	Distillates, petroleum, hydrotreated light	< 0.1 %	3,484.7	399.6	< 0.1 %
1319-33-1	Ulexite	< 0.1 %	3,327.8	293.2	< 0.1 %
31726-34-8	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	< 0.1 %	2,038.7	244.3	< 0.1 %
129898-01-7	2-Propenoic acid, polymer with sodium phosphinate	< 0.1 %	1,887.9	188.5	< 0.1 %
1310-73-2	Sodium hydroxide (impurity)	< 0.1 %	1,697.3	155.3	< 0.1 %
64742-65-0	Distillates (petroleum), solvent-dewaxed heavy paraffinic	< 0.1 %	1,548.8	177.6	< 0.1 %
7727-54-0	Diammonium peroxidisulphate	< 0.1 %	1,173.7	74.5	< 0.01 %
111-30-8	Glutaraldehyde	< 0.1 %	1,125.7	127.3	< 0.1 %
1338-43-8	Sorbitan, mono-(9Z)-9-octadecenoate	< 0.01 %	580.8	66.6	< 0.01 %
9004-96-0	Ethoxylated oleic acid	< 0.01 %	484.0	55.5	< 0.01 %
7647-14-5	Sodium chloride	< 0.01 %	381.2	38.1	< 0.01 %
1303-96-4	Sodium Tetraborate Decahydrate	< 0.01 %	367.8	32.4	< 0.01 %
12125-02-9	Ammonium chloride	< 0.01 %	290.4	33.3	< 0.01 %
9000-70-8	Gelatins	< 0.01 %	240.0	28.8	< 0.01 %
10043-52-4	Calcium Chloride	< 0.01 %	192.7	19.2	< 0.01 %
25038-72-6	Vinylidene chloride/methylacrylate copolymer	< 0.01 %	136.4	9.1	< 0.001 %
110-17-8	but-2-enedioic acid	< 0.001 %	87.6	7.7	< 0.001 %
61789-77-3	Dicoco dimethyl quaternary ammonium chloride	< 0.001 %	84.9	10.2	< 0.001 %
84133-50-6	Alcohols, C12-14-secondary, ethoxylated	< 0.001 %	67.8	7.8	< 0.001 %
7631-86-9	Non-crystalline silica (impurity)	< 0.001 %	38.6	4.6	< 0.001 %
111-46-6	2,2''-oxydiethanol (impurity)	< 0.001 %	20.4	2	< 0.001 %
79-06-1	2-Propenamid (impurity)	< 0.001 %	19.2	2.2	< 0.001 %
67-63-0	Propan-2-ol	< 0.001 %	17.0	2	< 0.001 %
7447-40-7	Potassium chloride (impurity)	< 0.0001 %	6.1	0.6	< 0.0001 %
595585-15-2	Diutan gum	< 0.0001 %	4.4	0.4	< 0.0001 %
14807-96-6	Magnesium silicate hydrate (talc)	< 0.0001 %	4.2	0.3	< 0.0001 %
9002-84-0	poly(tetrafluoroethylene)	< 0.0001 %	1.8	0.1	< 0.0001 %
		100 %	10,670,297 lbm	1,267,853 gal	100 %

** Mix water is supplied by the client. Schlumberger has performed no analysis of the water and cannot provide a breakdown of components that may have been added to the water by third-parties.*

** The evaluation of attached document is performed based on the composition of the identified products to the extent that such compositional information was known to GRC - Chemicals as of the date of the document was produced. Any new updates will not be reflected in this document.*

Appendix A.3 Compiled List of January 2022 Chemicals

Schlumberger

Client:	Imperial Energy
Well:	Carpentaria-2H
Basin/Field:	
State:	
County/Parish:	
Case:	
Disclosure Type:	Pre-Job
Well Completed:	
Date Prepared:	11/15/2021
Report ID:	RPT-1407

Fluid Description(s)	
YF125FlexD:SW: HVFR 4,268,500 gal	Contains: Water, Natural Corrosion Inhibitor B499, Surfactant , Acid, Breaker J218, Breaker J475, Gel J580, Crosslinker J604, Friction Reducer, Dry High Viscosity Friction Reducer J711, Scale Inhibitor, Clay Control Agent, Myacide GA 25, 100 Mesh Sand, Activator

† Proprietary Technology

The total volume listed in the tables above represents the summation of water and additives. Water is supplied by client.

CAS Number	Chemical Name	Mass Fraction	Mass	Volume	Volume Fraction
-	Water (Including Mix Water Supplied by Client)*	~ 99 %	35,486,603.8	4,250,668.1	~ 99 %
14808-60-7	Quartz, Crystalline silica	< 1 %	97,862.0	4,510.2	< 1 %
67-48-1	2-hydroxy-N,N,N-trimethylethanaminium chloride	< 1 %	66,405.4	7,233.8	< 1 %
9000-30-0	Guar gum	< 1 %	36,182.3	4,335.6	< 1 %
1319-33-1	Ulexite	< 0.1 %	13,426.1	1,182.9	< 0.1 %
107-21-1	Ethylene Glycol	< 0.1 %	12,553.7	1,162.2	< 0.1 %
7727-54-0	Diammonium peroxidisulphate	< 0.1 %	11,119.1	666.2	< 0.1 %
1310-73-2	Sodium hydroxide (impurity)	< 0.1 %	7,872.6	720.3	< 0.1 %
25085-02-3	Acrylamide sodium acrylate copolymer	< 0.1 %	5,085.9	761.8	< 0.1 %
31726-34-8	Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	< 0.1 %	4,830.0	578.8	< 0.1 %
129898-01-7	2-Propenoic acid, polymer with sodium phosphinate	< 0.1 %	4,471.6	446.5	< 0.1 %
111-30-8	Glutaraldehyde	< 0.01 %	3,200.1	361.8	< 0.01 %
7647-01-0	Hydrochloric acid	< 0.01 %	2,503.6	300.0	< 0.01 %
1303-96-4	Sodium Tetraborate Decahydrate	< 0.01 %	1,483.9	130.7	< 0.01 %
7647-14-5	Sodium chloride	< 0.01 %	903.0	90.2	< 0.01 %
7783-20-2	Ammonium sulfate	< 0.01 %	862.4	86.1	< 0.01 %
38193-60-1	Acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer	< 0.01 %	634.3	63.3	< 0.01 %
25038-72-6	Vinylidene chloride/methylacrylate copolymer	< 0.01 %	608.4	36.4	< 0.001 %
10043-52-4	Calcium Chloride	< 0.01 %	456.3	45.6	< 0.01 %
110-17-8	but-2-enedioic acid	< 0.001 %	353.3	31.1	< 0.001 %
61789-77-3	Dicoco dimethyl quaternary ammonium chloride	< 0.001 %	201.2	24.1	< 0.001 %
9000-70-8	Gelatins	< 0.001 %	160.0	19.2	< 0.001 %
7631-86-9	Non-crystalline silica (impurity)	< 0.001 %	90.7	10.9	< 0.001 %
136793-29-8	Polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate	< 0.001 %	66.3	6.6	< 0.001 %
111-46-6	2,2''-oxydiethanol (impurity)	< 0.001 %	48.3	4.8	< 0.001 %
57-13-6	Urea	< 0.001 %	41.5	4.1	< 0.001 %
67-63-0	Propan-2-ol	< 0.001 %	40.2	4.8	< 0.001 %
14807-96-6	Magnesium silicate hydrate (talc)	< 0.0001 %	18.6	1.1	< 0.0001 %
595585-15-2	Diutan	< 0.0001 %	17.7	1.6	< 0.0001 %
7447-40-7	Potassium chloride (impurity)	< 0.0001 %	14.5	1.4	< 0.0001 %
7757-82-6	Sodium sulfate	< 0.0001 %	8.3	0.8	< 0.0001 %
9002-84-0	poly(tetrafluoroethylene)	< 0.0001 %	7.9	0.5	< 0.0001 %
79-06-1	2-Propenamid (impurity)	< 0.0001 %	2.1	0.2	< 0.00001 %
64-02-8	Tetrasodium ethylenediaminetetraacetate	< 0.00001 %	1.2	0.1	< 0.00001 %
63148-62-9	Dimethyl siloxanes and silicones	< 0.00001 %	0.8	0.1	< 0.00001 %
67762-90-7	Siloxanes and silicones, dimethyl, reaction products with silica	< 0.00001 %	0.1	0.0	< 0.00001 %
556-67-2	Octamethylcyclotetrasiloxane	< 0.00001 %	0.1	0.0	< 0.00001 %
541-02-6	Decamethyl cyclopentasiloxane	< 0.00001 %	0.0	0.0	< 0.00001 %
7758-98-7	Copper(II) sulfate	< 0.00001 %	0.0	0.0	< 0.00001 %
540-97-6	Dodecamethylcyclohexasiloxane	< 0.00001 %	0.0	0.0	< 0.00001 %
		100 %	35,758,155 lbm	4,273,494 gal	100 %

** Mix water is supplied by the client. Schlumberger has performed no analysis of the water and cannot provide a breakdown of components that may have been added to the water by third-parties.*

** The evaluation of attached document is performed based on the composition of the identified products to the extent that such compositional information was known to GRC - Chemicals as of the date of the document was produced. Any new updates will not be reflected in this document.*

Appendix B Potential Risk to Groundwater from Hypothetical Water Releases

Potential Risk to Groundwater from Hypothetical Water Releases

Imperial Oil & Gas and Imperial Oil & Gas A Exploration Permits (167, 168, 169, 184, 187, 198 & 305)

Prepared for:

INGAUGE
Well Engineering & Project Management
Reliable I Experienced I Engaged

Prepared by:

EHS Support

December 2021

Document Control

PROJECT DETAILS

Project No.:	04921.0000
Report Revision No.:	1
Date of Issue:	01/11/2023
Project Manager:	Joe Hayes
Project Director:	Nigel Goulding

REPORT DETAILS

Title:	Potential Risk to Groundwater from Hypothetical Water Releases
Main Author(s):	Chris Smitt, Ben Petrides (Rev 0) Rebecca Fraser (Rev 1 - VLEACH model updates for chloride)
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Client:	inGauge Energy Australia
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DISTRIBUTION LIST

Date	No. of Copies	Company/Organisation	Name	Issue type
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Note:
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REVISION HISTORY

Date	Revision #	Status / Summary of Key Changes
21/12/2021	A	Draft for client review
14/04/2023	0	Issued as final. Added revision history and corrected revision numbers.
01/11/2023	1	VLEACH modelling completed for chloride in lieu of sodium.

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Table of Contents

1 Introduction 1

1.1 Objective 1
1.2 Scope of Work 1
1.3 Area of Interest 1

2 Overview of Hydrogeology/Geology 3

2.1 Basins and Sub-basins 3
2.2 Stratigraphic Overview in Each Exploration Permit 7
2.2.1 Eastern Tenements 7
2.2.1.1 EP 184 7
2.2.1.2 EP187 10
2.2.2 Western Tenements 12
2.2.2.1 EP167 12
2.2.2.2 EP168 13
2.2.2.3 EP169 13
2.2.2.4 EP198 14
2.2.2.5 EP305 14

3 Analytical Assessment (Methodology) 16

3.1 Lateral Spreading of Fluid/Runoff 16
3.1.1 Water Pooling on Flat Surfaces 17
3.2 Infiltration into Unsaturated Zone 17
3.2.1 Green and Ampt Infiltration Model 18
3.2.2 Darcy Infiltration Model 19
3.3 Leaching within the Unsaturated Zone 19
3.3.1 VLEACH Unsaturated Zone Leaching Model 19

4 Analytical Assessment (Approach & Results) 20

4.1 Overland Flow 20
4.1.1 Overland Flow on Flat Surfaces 20
4.2 Green and Ampt Infiltration Model 22
4.3 Darcy Infiltration Model 22
4.4 VLEACH Model 25

5 Discussion 29

6 Limitations 30

7 References 31

List of Tables

Table 2-1 Basins and Sub-basins Relevant to the Areas of Interest
Table 2-2 Basin Summary and Relationships
Table 2-3 Available Stratigraphic Information from Existing Drillholes and Wells
Table 2-4 EP184 – Generalised Stratigraphy
Table 2-5 EP187 – Generalised Stratigraphy
Table 2-6 EP167 – Generalised Stratigraphy
Table 2-7 EP168 – Generalised Stratigraphy
Table 2-8 EP169 (Central and East) – Generalised Stratigraphy
Table 2-9 EP169 (West) – Generalised Stratigraphy
Table 2-10 EP198 (Central and East) – Generalised Stratigraphy
Table 2-11 EP198 (West) – Generalised Stratigraphy
Table 2-12 EP305 – Generalised Stratigraphy
Table 3-1 Relative Permeability k_r, for Different Scenarios of Accidental Release
Table 3-2 Values of Intrinsic Permeability and Kinematic Viscosity for Sand and Clay
Table 4-1 Simplified Stratigraphy -Top 50 m Profile
Table 4-2 Modelling Input Parameters
Table 4-3 Model Results - Pooled Water Area
Table 4-4 Selected Drilling Mud Chemistry
Table 4-5 Constituent Properties
Table 4-6 Chloride VLEACH Input Parameters

List of Figures

Figure 1-1 Imperial Oil & Gas and Imperial Oil & Gas A Exploration Permits in the Northern Territory and Major Basins and Sub-basins
Figure 2-1 Eastern Tenements and Basins (EP184 and EP 187)
Figure 2-2 Western Tenements and Basins (EP167-9, EP198 and EP305)
Figure 2-3 Exploration Permit Areas – Well and Borehole Details
Figure 2-4 Location of the McArthur Basin and Beetaloo Sub Basin along with generalised stratigraphy within the area of Tanumbirini-1. Reference used: inGauge (2020) (geological cross-section), and Close et al (2016) (SEEBASE™ depth-to-basin image and stratigraphic column)
Figure 2-5 Shallow Lithology from well “Tanumbirini-1”
Figure 3-1 Conceptualisation of the Green-Ampt Model and the Remaining Runoff
Figure 3-2 VLEACH process diagram
Figure 4-1 Results of the Green-Ampt Analytical Model for Limestone and Siltstone
Figure 4-2 Conceptualisation of Drilling Mud Leaching
Figure 4-3 VLEACH Results – Organic Constituents
Figure 4-4 VLEACH Results – Chloride

Acronyms

atm-m^3/mol	atmospheric pressure and cubic metres per mole
BMR	Bureau of Mineral Resources
CEC	cation exchange capacity
CLA	Cambrian Limestone Aquifer
EC	electrical conductivity
EP	Exploration Permit
mbgl	metres below ground level
MITC	methylisothiocyanate
NMBCT	Northern McArthur Basin Central Trough
SWL	standing water level

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Units of Measure

Area	
ha	hectare
m^2	square metres
Density	
kg/m^3	kilograms per cubic metre
Electrical Conductance	
µS/cm	micro Siemen per centimetre
mV	millivolt
Length	
µm	micrometres
cm	centimetres
km	kilometres
m	metres
Mass	
µg	micrograms
kg	kilograms
mg	milligrams
t	metric tonnes
Concentration by Mass	
µg/kg	microgram per kilogram
mg/kg	milligram per kilogram
Pressure	
kPa	kilopascals
Pa	Pascals
Temperature	
°C	degrees Celsius
°F	degrees Fahrenheit
K	kelvin
Velocity	
m/d	metres per day
m/s	metres per second
L/s	Litres per second
Volume	
µL	microlitres
cm^3	cubic centimetre
GL	gigalitre
L	litres
m^3	cubic metre
mL	millilitres
ML	megalitre
Concentration by Volume	
µg/L	microgram per litre
mg/L	milligram per litre
ppmv	parts per million by volume
ppbv	parts per billion by volume

1 Introduction

This report provides an assessment of the potential for impacts on groundwater associated with shale gas activities of Imperial Oil & Gas and Imperial Oil & Gas A in the Northern Territory (NT). For the purpose of this assessment the primary mode of potential impact was identified as an accidental release to the land surface and the resulting radial land flow and sub-surface infiltration. The technical assessment and modelling are provided in the following sections.

1.1 Objective

The objective of this assessment is to define the potential extent of the area impacted by a release or "spill" of fluids and the likelihood of migration to groundwater. Specifically, the following questions were addressed:

1. Using three spill scenarios (1,000 L, 100,000 L and 1 ML), determine the maximum pooled area in which a spill would inundate.
2. Over the size of the pooled area, determine infiltration rates to gain an understanding of vertical groundwater movement and associated travel time.
3. Evaluate the potential impacts on groundwater if the spilt fluid contained drilling muds (where muds are blended with soils).

1.2 Scope of Work

To meet the objectives described above, the following work tasks were undertaken:

1. Establish applicable soil/aquifer characteristics within the areas of interest based on a literature review, available stratigraphic information from the Petroleum Onshore Information Northern Territory (POINT) web-based data catalogue and other literature (as appropriate).
2. Assess the water pooling area on a flat surface using the formulae proposed by Grimaz et al. (2007).
3. Assess the infiltration capacity of surface soils and ponding time using the analytical Green-Ampt infiltration equation (Green and Ampt, 1911).
4. Assess the infiltration velocity and depth once surface soils become saturated using Darcy's Law (Darcy, 1856).
5. Evaluate the potential impacts on groundwater (using VLEACH) if the spilt fluid contained drilling muds (where muds are blended with soils).

1.3 Area of Interest

This assessment of the potential for impacts on groundwater associated with shale gas activities in the Northern Territory is applicable to Exploration Permits (EP) 167, 168, 169, 184, 187, 198 and 305 only. The EP's are shown on **Figure 1-1**, along with the major Basins and Sub-basins.

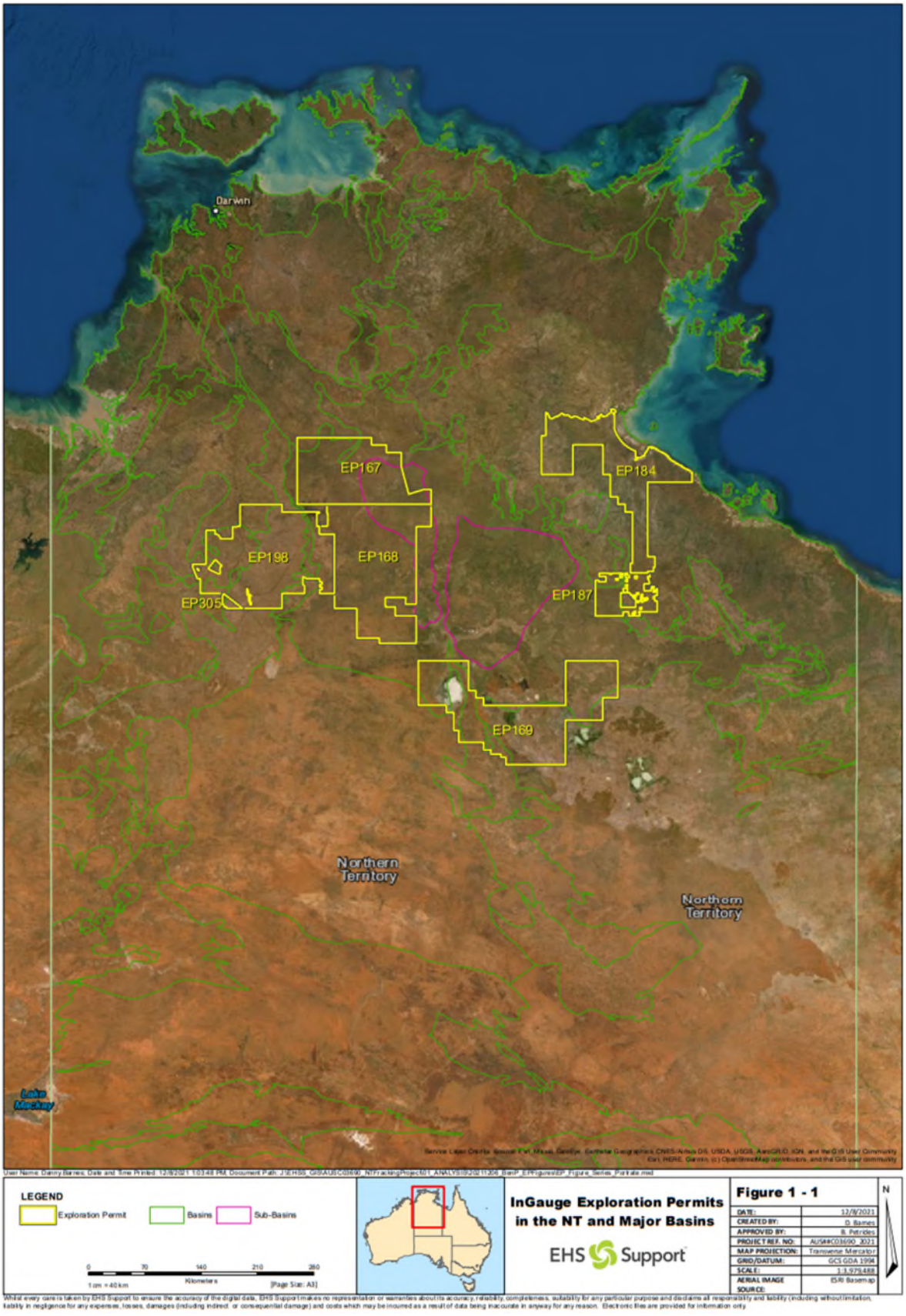


Figure 1-1 Imperial Oil & Gas and Imperial Oil & Gas A Exploration Permits in the Northern Territory and Major Basins and Sub-basins

2 Overview of Hydrogeology/Geology

Imperial Oil & Gas and Imperial Oil & Gas A plan to progressively explore its NT tenements, following the drilling and present appraisal of Carpentaria-1 and Carpentaria-2 in EP187. Carpentaria-2 encountered thick liquid rich gas shales across the four stacked Velkerri Formation pay zones with strong gas shows across the target formations and live gas bleeding from core samples. Well log interpretation indicated a strong correlation in thickness and rock characteristics of the four stacked shale targets to the Carpentaria-1 location.

Imperial Oil & Gas and Imperial Oil & Gas A are presently planning for exploration drilling on EP167 and EP168, as future stages. This assessment addresses all of their NT tenements (see **Table 2-1** and **Figure 1-1**), but given the immediate focus, the most detail is provided for EP167, EP168, EP184 and EP187. As additional tenements are planned for exploration, where relevant, this assessment will be updated with more detailed and site-specific information, if required.

2.1 Basins and Sub-basins

Table 2-1 presents Imperial Oil & Gas and Imperial Oil & Gas A tenements and the associated geological basins (sub basins where relevant). **Table 2-2** provides a summary of the basins and the inter-relationships. These tenements are split into two main areas:

- Eastern: EP184 and EP187, which are predominantly located in the McArthur Basin, but also within the Carpentaria and Georgia Basins; and
- Western: EP167-169, EP198 and EP305, which are spread over a number of basins including the Birrindudu, Carpentaria, Daly, Georgina, Victoria and Wiso Basins.

Figure 2-1 presents the Eastern tenements and relevant basins while **Figure 2-2** presents the Western tenements and relevant basins.

Table 2-1 Basins and Sub-basins Relevant to the Areas of Interest

Exploration Permit	Owner	Basin(s)	Sub-basin
Eastern			
EP184	Imperial Oil & Gas Pty Ltd	McArthur	-
EP187	Imperial Oil & Gas Pty Ltd	Carpentaria, Georgina, McArthur	-
Western			
EP167	Imperial Oil & Gas A Pty Ltd	Carpentaria and Daly	Beetaloo
EP168	Imperial Oil & Gas A Pty Ltd	Carpentaria	Beetaloo
EP169	Imperial Oil & Gas A Pty Ltd	Carpentaria, Georgina, Wiso	-
EP198	Imperial Oil & Gas A Pty Ltd	Birrindudu, Carpentaria, Victoria, Wiso	-
EP305	Imperial Oil & Gas A Pty Ltd	Victoria	-

Table 2-2 Basin Summary and Relationships

Basin	Age (Ma)	Thickness (km)	Lithology	Relationship
Carpentaria	–5 - 205	5	Sedimentary: sandstone, mudstone, limestone	Unconformably overlies the sedimentary rocks of Palaeoproterozoic Murphy Inlier, Paleo-Mesoproterozoic McArthur and South Nicholson basins, Neoproterozoic to Palaeozoic Georgina Basin and Palaeozoic Daly Basin.
Wiso	360 – 540	<0.3 to 3	Sedimentary: dolostone, limestone, shale, sandstone, siltstone.	Faulted against Palaeo-Neoproterozoic metamorphic rocks of the Aileron Province to the south. Unconformably overlies Palaeoproterozoic rocks of the Tanami Region to the west, Tennant Region to the east, and the Palaeo-Mesoproterozoic Birrindudu Basin to the northwest. Cretaceous rocks of the Carpentaria Basin cover its northern margin.
Georgina	355 -850	3.7	Sedimentary: dolostone, limestone, shale, sandstone, siltstone.	Unconformably overlies Palaeoproterozoic Murphy, Warramunga and Davenport provinces, Palaeo-Mesoproterozoic McArthur and South Nicholson basins and Lawn Hill Platform, and in fault contact with Palaeo-Neoproterozoic Aileron Province. Interpreted to be contiguous with Neoproterozoic to Palaeozoic Wiso and Daly basins that developed as distinct depocentres isolated by basement highs formed from the Cambrian Kalkarindji Province. Unconformably overlain by Mesozoic Carpentaria and Eromanga basins.
Daly	4–0 - 520	1	Sedimentary: limestone, dolostone, sandstone, siltstone, conglomerate	Unconformably overlies the Palaeoproterozoic Pine Creek Orogen and Palaeo-Mesoproterozoic Birrindudu Basin to the north and east and Neoproterozoic Victoria Basin to the west. Overlain by Mesozoic Carpentaria Basin on its southern margin
Victoria	7–0 - 850	0.950	Sedimentary: dolostone, sandstone, limestone, shale.	Unconformably overlies Palaeoproterozoic Pine Creek Orogen and Palaeo-Mesoproterozoic Birrindudu Basin. Unconformably overlain by Neoproterozoic Wolfe Basin, Neoproterozoic to Palaeozoic Wiso Basin, Palaeozoic Daly Basin and Cambrian Kalkarindji Province.
Beetaloo Sub-basin	1320- 1650	10	Sedimentary and minor volcanic: dolostone, sandstone, shale, felsic and mafic volcanic rocks.	The Beetaloo Sub-basin is a structural component of the Proterozoic greater McArthur Basin. It consists of two discrete subsurface volumes of sedimentary rock, typically bounded by faults, containing the thickest preserved formations that host significant hydrocarbon resources. Significant thicknesses of Mesoproterozoic sediment accumulated in the Beetaloo Sub-basin relative to adjacent areas (Munson, 2016). The sub-basin lies entirely under the cover of younger basin sediments of the Neoproterozoic Centralian A Superbasin, the Paleozoic Centralian B Superbasin (including the Georgina, Wiso and Daly basins) and the Mesozoic Carpentaria Basin.
McArthur	14–0 - 1800	12	Sedimentary and minor volcanic: dolostone, sandstone, shale, felsic and mafic volcanic rocks.	Unconformably overlies Palaeoproterozoic Pine Creek Orogen, Murphy Province and Arnhem Province to the northwest, southeast and northeast respectively. Unconformably overlain by the Palaeozoic Arafura, Georgina and Mesozoic Carpentaria basins. Interpreted to be contiguous under cover with the Palaeo-Mesoproterozoic Birrindudu Basin and Tomkinson Province.
Birrindudu	15–0 - 1780	10	Sedimentary: sublithic arenite, quartz arenite, siltstone, shale, conglomerate, stromatolitic chert, limestone, glauconitic sandstone.	Unconformably overlies Palaeoproterozoic Pine Creek Orogen to the north. Unconformably overlain by Palaeozoic Wiso and Daly basins to the east; by Cambrian Ord Basin to southwest; by Neoproterozoic Wolfe Creek Basin to west and Neoproterozoic Victoria Basin to the north; and in places, by Cambrian Kalkarindji Province and patchy sedimentary rocks of basin-margin Mesozoic sandstone. Towards the south is underlain by Palaeoproterozoic metasediments and granites of Tanami Region. In northwest, in faulted contact with Palaeozoic–Mesozoic Bonaparte Basin and Palaeoproterozoic rocks of Halls Creek Orogen.

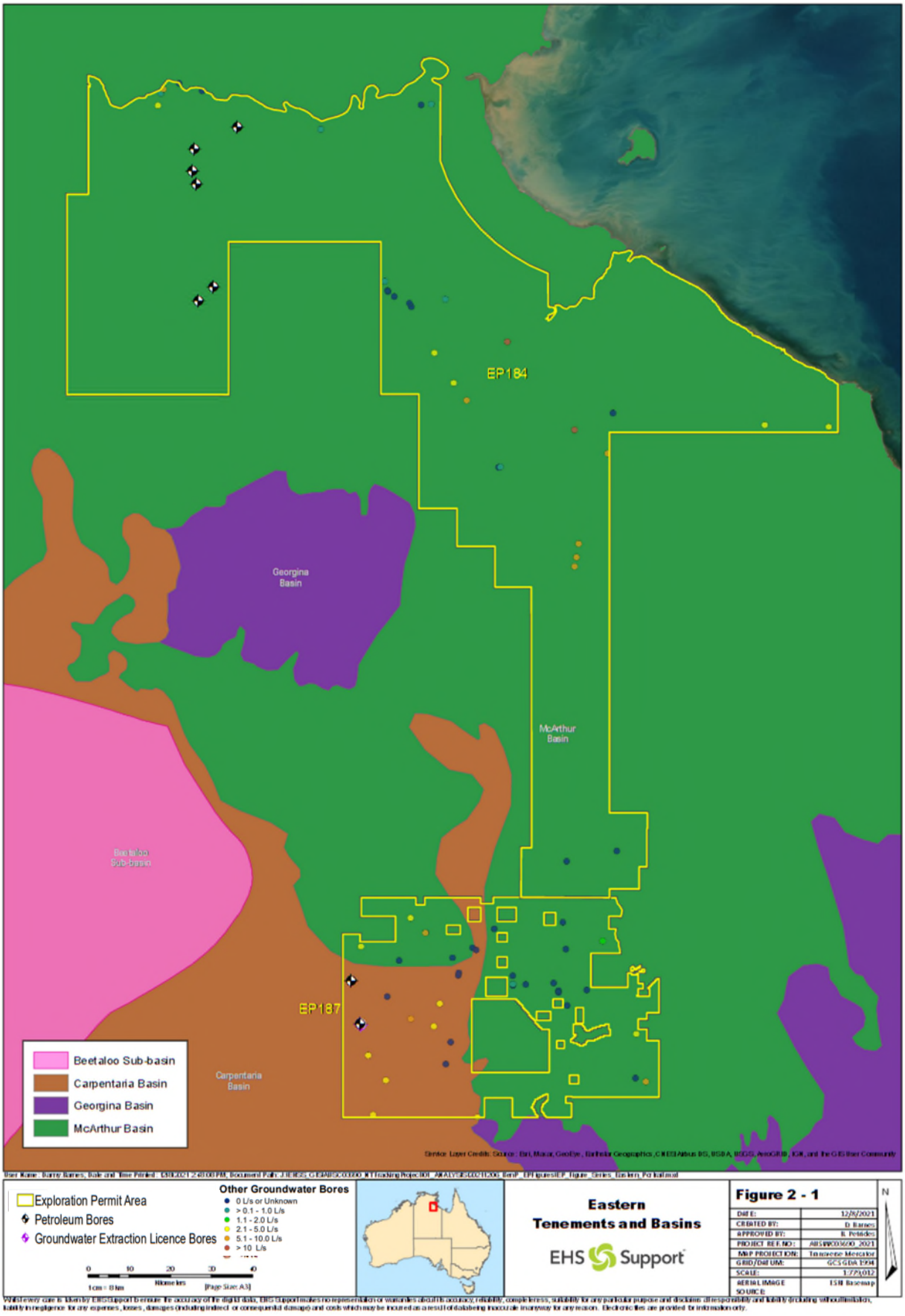


Figure 2-1 Eastern Tenements and Basins (EP184 and EP 187)

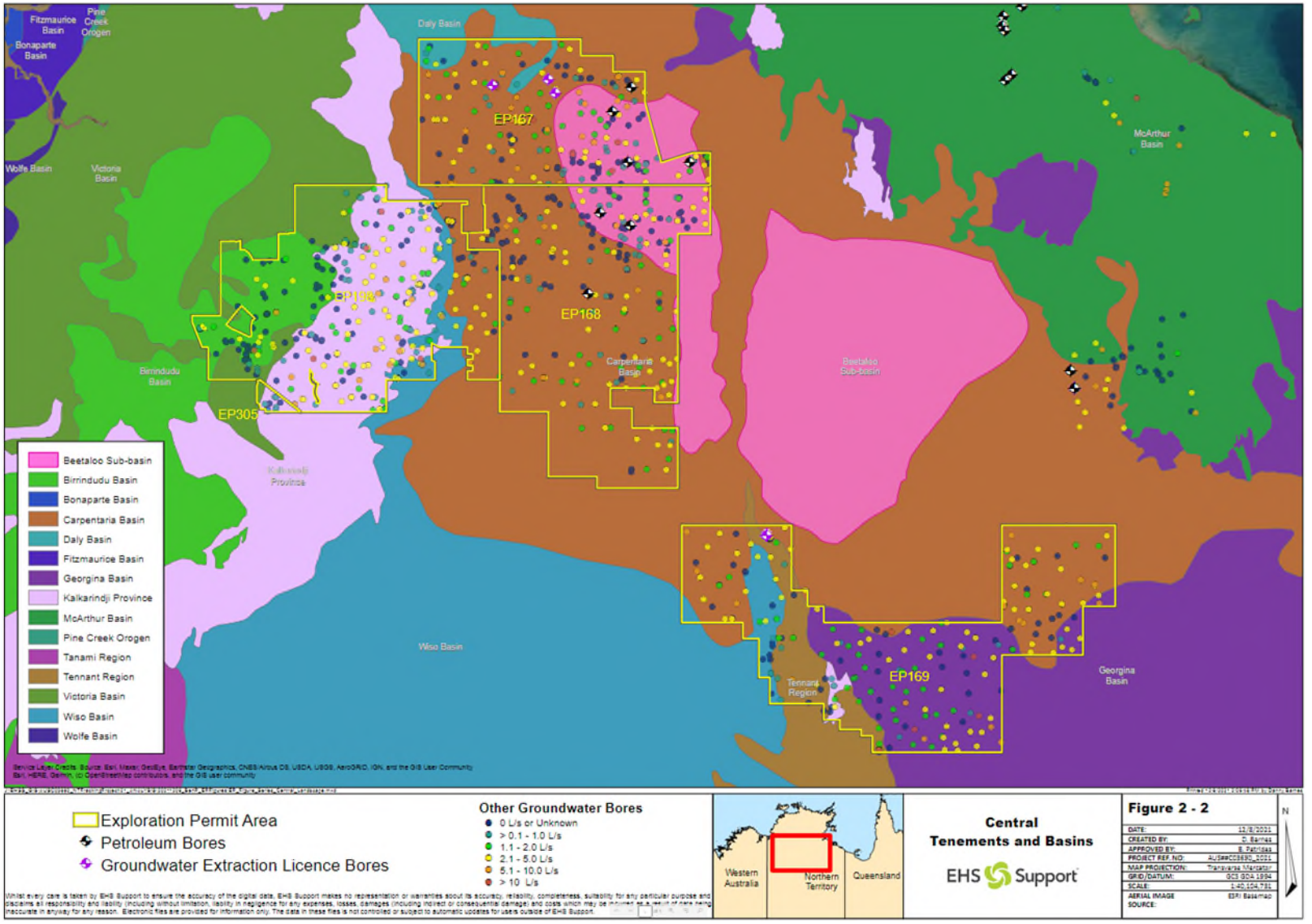


Figure 2-2 Western Tenements and Basins (EP167-9, EP198 and EP305)

2.2 Stratigraphic Overview in Each Exploration Permit

The shallow (<100 m) hydrostratigraphic sequence within each EP was evaluated by reviewing petroleum drillholes, where present, groundwater extraction licence well construction logs and other stock and domestic supply well construction logs. These shallow sequences are most susceptible to impacts associated by a release or "spill" of fluids. The breakdown of available information is presented in **Table 2-3**.

Table 2-3 Available Stratigraphic Information from Existing Drillholes and Wells

Exploration Permit	# of Petroleum Drillholes	# of Groundwater Extraction Licenced Wells	# of Other Stock and Domestic Supply Wells
EP184	7	0	32
EP187	2	2	40
EP167	4	3	213
EP168	3	0	223
EP169	0	5	301
EP198	0	0	361
EP305	0	0	10

Figure 2-3 shows the petroleum drillholes, groundwater extraction licenced wells and stock and domestic supply wells in each of the exploration permits.

2.2.1 Eastern Tenements

2.2.1.1 EP 184

2.2.1.1.1 Geological Setting

The regional geology of the McArthur River Basin is well summarised by Jackson et al. (1987), Plumb and Roberts (1992), Plumb et al. (1990), Madigan and Rawlings (1994) and Pietsch et al. (1994). The Middle Proterozoic McArthur Basin of Central Australia outcrops over an area of 200 000 km^2, in the Northern Territory, with a relatively unknown, but large, section which sub-crops below younger sequences.

The Northern McArthur Basin within EP184 is dominated by the Walker Trough and the Urapunga Fault Zone, a northwest trending, extensively faulted zone approximately 50 to 70 km wide. Gentle warping and folding can be related to the faults. Fold axis generally trend north-northwest and locally east-northeast and northwest to west-northwest. It is estimated that during deposition of the McArthur Basin a number of subsidence events due to rifting associated with extension along pre-existing basement structures probably occurred.

The basin contains up to 12 relatively undeformed and un-metamorphosed sedimentary rocks comprising clastics, evaporites and carbonates. The stratigraphy is subdivided into four stratigraphic groups separated by regional unconformities. The four stratigraphic groups of the Middle Proterozoic are the Tawallah Group, McArthur Group, Nathan Group, and the Roper Group. An unnamed sequence of Neo-Proterozoic sediments accumulated over the Roper Group.

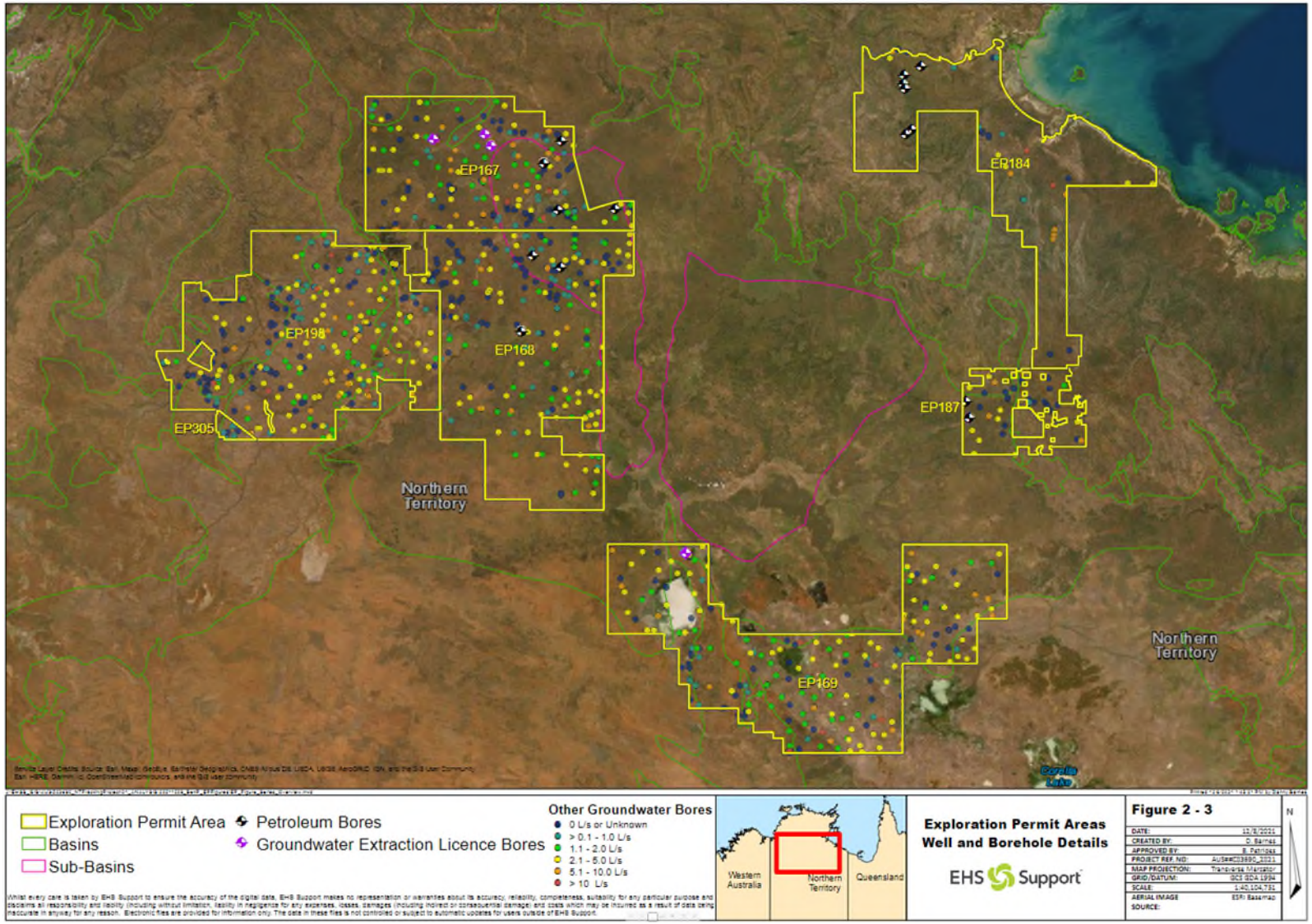


Figure 2-3 Exploration Permit Areas – Well and Borehole Details

The main structural features reflecting the tectonic evolution of the McArthur Basin are; east-west trending basement ridges such as the Murthy and the Urapunga Ridges; northwest-trending strike-slip faults, such as the Calvert, Mallapunyah and Bulman Faults; and north-trending high angle older normal faults with later inversion, such as the Emu, Tawallah and Four Arches faults.

Differential subsidence of the Walker Trough probably started during deposition of the Lower McArthur Group and continued, to a lesser extent, during the deposition of the Nathan Group (Jackson, et.al., 1987). Thickening of the Roper Group, to 5 km on the Bauhinia Shelf, west of the Abner Range area reflects a shift of the basin depocenter during the deposition of the Roper Group.

The Tawallah Group is the lowermost of the four major sequences; it is up to 4,500 m thick and represents the economic or effective basement. The Tawallah Group consists mainly of sandstones with subordinate finer grained clastics, volcanics and rare carbonates.

The McArthur and Nathan Groups overlay the Tawallah Group; they have a combined thickness of between 3,000 and 5,500 m. They are mostly stromatolitic and evaporitic dolostones interbedded with lesser siltstones and shales.

The McArthur and Nathan Group sediments were deposited in a variety of environments including marginal marine, lagoonal, lacustrine and fluvial. The McArthur and Nathan Groups are potentially a source of the hydrocarbons encountered in wells.

The uppermost unit, the Roper Group varies between 2,500 and 4,000 m in thickness. The Roper Group thickens to the southwest. It consists of alternating quartz arenites, siltstones and shales. The Roper Group unconformably overlies the McArthur and the Nathan Groups.

The sedimentary sequences within the Roper Group have significant lateral extent, with more uniform facies when compared to the underlying successions, of the Tawallah, McArthur and Nathan Groups. The estimated age of the Roper Group is at least 1,430 Ma. An un-named succession of sandstones and shales of probable Neo-Proterozoic age, overlays the Roper Group, these have a maximum thickness in excess of 600 m.

2.2.1.1.2 Stratigraphy

Within the McArthur Basin, limited petroleum exploration has been undertaken. However, stratigraphic interpretations have been inferred from Bureau of Mineral Resources (BMR) drilling in the Urapunga region (north of EP187, in the vicinity of EP184). This shows the Barkly Group and some of the Roper Group missing. Importantly, this means they are not in connection to the Cambrian Limestone Aquifers (CLA) comprising the Oolloo, Jindickin, Tindall, Anthony Lagoon and Gum Ridge aquifers, an important water resource found in the Beetaloo sub-basin. It is also likely in this area that the shallow aquifers are hosted in the Bukalorkmi Sandstone (formally the McMinn Formation) or Kyalla Shale. The Bukalorkmi Sandstone is only between 10 to 20m thick and comprises white, light grey to brown, fine to coarse-grained and locally granule-rich quartz sandstone. This Formation also hosts the Roper Field kimberlitic dykes and also supports contact springs. These springs are defined where a more permeable rock, such as sandstone, lies above a less permeable rock, such as siltstone or dolerite, and are often seen at the base of escarpments. Where springs occur as a result of fractured and karstic rocks (such as dykes), significant flows are possible. In addition, airlift tests undertaken in bores RN35878, RN35879, and RN036300 (screened in the Bukalorkmi Sandstone) airlifted 5 L/s, however pump tests undertaken on RN35879 and RN36300 recommended rates at 0.7 and 0.5 L/s respectively. The water quality from the

Bukalorkmi Sandstone aquifer had a pH between 6.3 and 7.2 and Electrical Conductivity (EC) of between 264 and 399 µS/cm (Matthews, 2008).

EP184 covers an area of approximately 11,161 km^2. Seven petroleum wells have been drilled in this EP, focussed in the north-western corner, south of the Roper River. Based on the basic well completion reports and the well construction logs from surrounding stock and domestic supply wells, the generalised lithology is described in **Table 2-4**. The fractured and weathered rocks are a minor groundwater resource with recorded yields up to 1 L/sec.

Table 2-4 EP184 – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	50	Interbedded siltstone/mudstone	Kyalla Member
50	120	Massive sandstone	Moroak Sandstone
>120		Mudstone and fine sandstone	Velkerri Formation of the Roper Group

2.2.1.2 EP187

Within and surrounding EP187, the shallowest hydrogeological unit of interest is the CLA defined as the Top Springs Limestone (also commonly referred to as the Tindal Limestone or Gum Ridge Formation) depending on which part of the basin you are in. The unit comprises massive and commonly dolomitised (and often fractured and karstic) limestone beds with minor siliclastic mudstone.

Santos exploration bore Tanumbirini-1 is located approximately 40 km west of EP187 and indicates that the Top Springs Limestone can be found at a depth of 52 mbgl with a thickness of 150m. **Figure 2-4** shows the location of Tanumbirini-1 and **Figure 2-5** shows the stratigraphy. However, it is anticipated that this formation shallows and thins towards EP187 where it potentially outcrops at the basin margin. Where the CLA is absent, the deeper Bukalorkmi Sandstone (formally referred to as the McMinn Formation) is a potential highly permeable aquifer.

In the vicinity of exploration bore Tanumbirini-1, the CLA is confined by Cretaceous siltstones mudstones, however underlying EP187, the CLA (Gum Ridge Formation) outcrops. The permeability of the CLA is highly dependent on the development of dissolution and fracture features (Fulton and Knapton, 2015). A review of water bores that intersect cavities or record circulation loss during drilling suggests that the karst development is widespread across the Beetaloo Sub-Basin and that aquifer permeability is generally not spatially correlated.

Fulton and Knapton, (2015), reported airlift yields range from 0.3 to 20 L/sec (average 3.5 L/sec), with the standing water level (SWL) in the Gum Ridge Formation ranging from 23 to 155 mbgl. Results from 21 pumping tests undertaken by WRD report a Transmissivity (T) range of 3 to 3,377 m^2/d. The lowest T values (less than 50 m^2/d) occur northwest of the basin where the CLA has limited saturated thickness and aquifer development is restricted to the unconformity with the underlying Antrim Plateau Volcanics (Yin Foo, 2000). Limited transmissivity would also be expected near the eastern basin boundary.

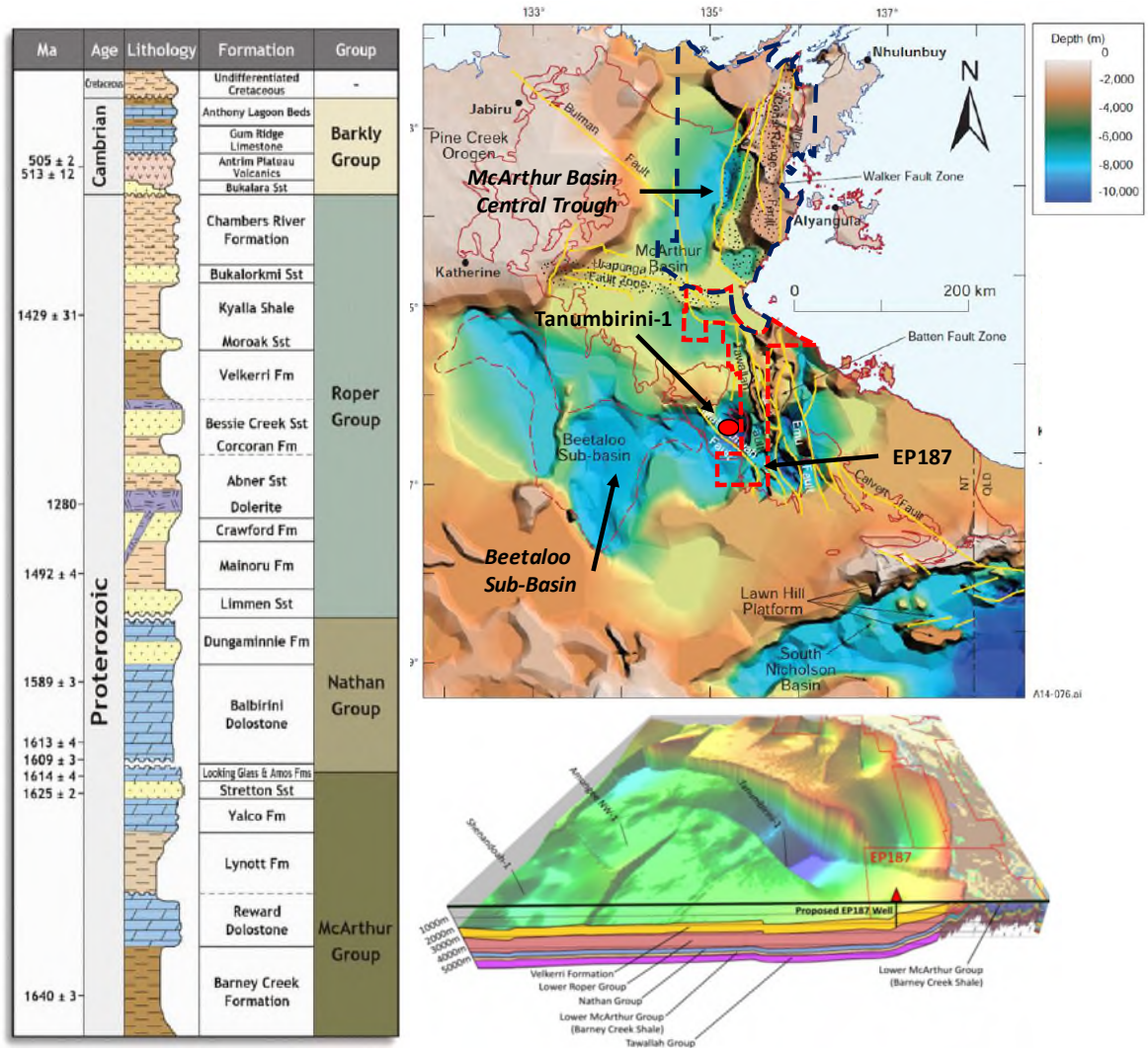


Figure 2-4 Location of the McArthur Basin and Beetaloo Sub Basin along with generalised stratigraphy within the area of Tanumbirini-1. Reference used: inGauge (2020) (geological cross-section), and Close et al (2016) (SEEBASE™ depth-to-basin image and stratigraphic column)

EP187 covers an area of approximately 2,986 km^2. Two petroleum wells have been drilled in this EP; Carpentaria 1 and Carpentaria 2 and based on the basic well completion reports the generalised lithology is described in **Table 2-5**. The major aquifer in the EP is the Gum Ridge Limestone or Tindall Limestone, which has a recorded yield of between 0.5 and 5 L/sec and the Anthony Lagoon Beds (which was identified during the drilling of Carpentaria 2 and is being monitored, see additional comments in **Section 2.2.2.3**).

Table 2-5 EP187 – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	50	Clay	-
50	100	Limestone	Gum Ridge Limestone/Anthony Lagoon Beds
>100		Sandstone	Bulkalara Sandstone

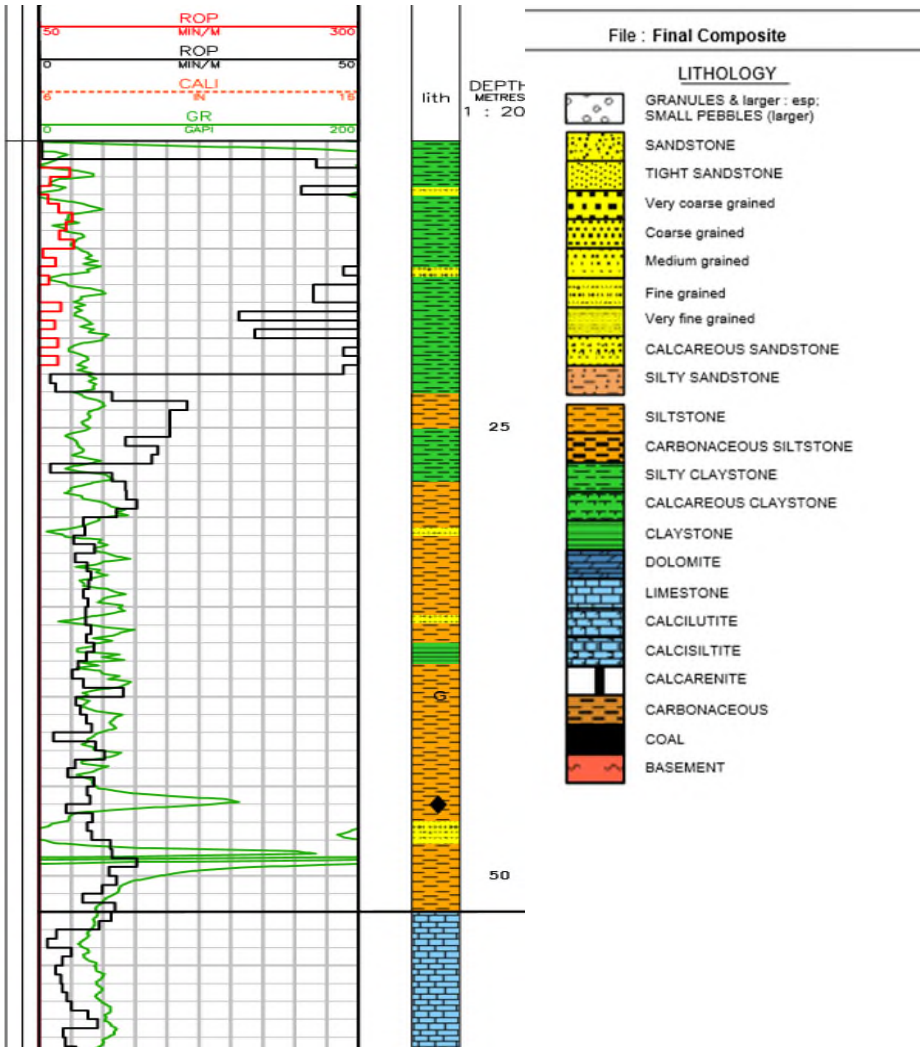


Figure 2-5 Shallow Lithology from well "Tanumbirini-1"

2.2.2 *Western Tenements*

2.2.2.1 EP167

EP167 covers an area of approximately 10,616 km^2. Four petroleum wells have been drilled in this EP; Sever 1, Wyworrie 1, Tarlee S3 and Birdum Creek 1, mostly within the Beetaloo sub-basin. Based on the basic well completion reports completed by Pangaea (NT) Pty Ltd and the well construction logs from the three groundwater extraction licenced wells, the generalised stratigraphy is described in **Table 2-6**. The major aquifer in the EP is the Tindall Limestone, which has a recorded yield of between 0.5 L/sec and 5 L/sec.

Table 2-6 EP167 – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	10	Clay	-
10	50	Limestone	Tindall Limestone
50	150	Basalt	Antrim Plateau Volcanics

2.2.2.2 EP168

EP168 covers an area of approximately 15,852 km^2. Three petroleum wells have been drilled in this EP, Tarlee 1, Tarlee 2 and Hidden Valley S2. Based on the basic well completion reports completed by Pangaea (NT) Pty Ltd, the generalised stratigraphy is described in **Table 2-7**. The major aquifer in the EP is the Tindall/Montejinni Limestone, which has a recorded yield of between 0.5 and 5 L/sec.

Table 2-7 EP168 – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	25	Clay	-
25	80	Limestone	Montejinni Limestone/Tindall Limestone Formation
>80		Basalt	Antrim Plateau Volcanics

2.2.2.3 EP169

EP169 covers an area of approximately 16,012 km^2. Petroleum wells have not been drilled within this EP, however there are a number of stock and domestic supply wells that have been drilled to ~150 mbgl. The Helen Springs 1:250,000 Hydrogeological Map (NT DIPE, 1992) provided additional conceptualisation supported by local groundwater well construction logs.

In the central and eastern part of the EP, the Anthony Lagoon Beds, comprising sandstone and dolomitic/siltstone/limestone and the Gum Ridge Formation comprising fossiliferous siltstone and chert and limestone form the major aquifer in the region (**Table 2-8**). Groundwater yields in these fractured and karstic rocks have been recorded between 5.0 and 15.0 L/sec.

Table 2-8 EP169 (Central and East) – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	10	Clay	-
5	100	Limestone	Anthony Lagoon Beds/Gum Ridge Formation

In the western and north-western part of the EP, outcropping sandstones and siltstones with minor dolomite of the Tomkinson Creek Beds also form aquifers in the region (**Table 2-9**). Groundwater yields in the Tomkinson Creek Beds have been recorded between 0.05 and 0.5 L/sec. Localised outcrop of the Helen Springs Volcanics and Montejinni Limestone have also been utilised.

Table 2-9 EP169 (West) – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	10	Clay	-
10	30	Gravel/Clay	-
30	100	Sandstone	Tomkinson Creek Beds

2.2.2.4 EP198

EP198 covers an area of approximately 15,341 km^2. Petroleum wells have not been drilled within this EP, however there are a number of stock and domestic supply wells that have been drilled to ~200 mbgl. In the central and eastern part of the EP, the Antrim Plateau Volcanics forms an aquifer in the region, comprising of basalt and interbedded sandstone. These volcanics are considered to be a regional aquitard in the region and is used as a local aquifer where groundwater supply from the limestone is not sufficient (Evans et al. 2020). This is underlain by the Jasper Gorge Formation/Stubb Formation comprising interbedded shale, siltstone and sandstone and the Weaner Formation (**Table 2-10**). Groundwater yields in the basalt have been recorded between 0 and 6 L/sec.

Table 2-10 EP198 (Central and East) – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	5	Clay	-
5	100	Basalt	Antrium Plateau Volcanics
<100		Sandstone	Jasper Gorge Formation/Stubb Formation

In the western part of the EP, outcropping sandstones and interbedded dolomitic siltstone of the Weaner Sandstone and Bynoe Formation also form aquifers in the region (**Table 2-11**). The Antrium Plateau Volcanics is also present in some areas in the west. Groundwater yields in the siltstone/dolomite have been recorded between 0 and 15 L/sec.

Table 2-11 EP198 (West) – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit
0	5	Clay	-
5	100	Dolomite/Siltstone	Weaner Sandstone/Bynoe Formation

2.2.2.5 EP305

EP305 covers an area of approximately 222 km^2. Petroleum wells have not been drilled within this EP, however there are a number of stock and domestic supply wells that have been drilled to ~130 mbgl. These stock and domestic supply wells target the Antrim Plateau Volcanics with recorded yields ranging from 0.0 to 1.0 L/sec. The SWL has been recorded between ~20 and 80 mbgl. Based on a review of the well construction logs from the 10 licensed groundwater extraction wells, and the Victoria River Downs 1:250,000 Hydrogeological Map (NT DIPE, 1997), the generalised stratigraphy is summarised in **Table 2-12**.

Table 2-12 EP305 – Generalised Stratigraphy

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit*
0	10	Clay	-
10	80	Basalt	Antrim Plateau Volcanics
80	150	Shale/sandstone	Jasper Gorge Sandstone

Depth From (mbgl)	Depth to (mbgl)	Lithology	Hydrogeological Unit*
>150		Dolomite/Limestone	Skull Creek Formation

* Based on Lithological mapping by M. Ahmad in 1972; Bore Report RN007339

3 Analytical Assessment (Methodology)

Liquid releases on a permeable soil surface undergo three main processes that control the extent of the release and the subsequent environmental impacts. These processes are:

- Overland flow (runoff);
- Evaporation; and
- Infiltration.

In this assessment, overland flow (also referred to as runoff) is assessed along with infiltration.

3.1 Lateral Spreading of Fluid/Runoff

Runoff of water as a fluid dynamical process has concurrently been an important research topic with surface water hydrology and is typically described with the use of the Saint Venant equations (Woolhiser and Liggett, 1967). However, only recently has runoff been coupled with surface infiltration at a spatial scale that can be applicable to point source flows, such as release from a pipeline. Esteves et al. (2000) contains a list of theoretical models that include the basic elements of a liquid release on land.

The approach adopted for this assessment is a progression of the Green and Ampt (1911) model (**Section 3.2.1**). In essence the Green-Ampt model approximates the curved soil moisture profiles allowing the calculation of the soils infiltration capacity. The remaining water balance component is therefore runoff. This is visually presented in **Figure 3-1**.

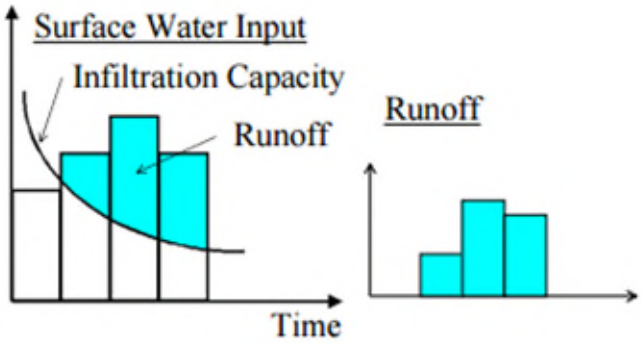


Figure 3-1 Conceptualisation of the Green-Ampt Model and the Remaining Runoff

Due to the regional approach and the complexity of this assessment, slight modifications to mathematical theory behind this and similar models were undertaken to predict the regional scale flow characteristics from a point source.

Whilst the Green-Ampt (1911) equation was used to assess the initial infiltration depths, modifications to the algorithm developed by Grimaz et al. (2007) and the Manning Kinematic Equation were adopted to model the remaining water assumed to be runoff. These analytical steps are provided in **Section 3.1.1**.

3.1.1 Water Pooling on Flat Surfaces

For instantaneous releases on flat surfaces (and assuming this water bypasses any bunded walls), the formulae (Equation 1) proposed by Grimaz et al. (2007) was used to estimate the area of the pool of liquid on flat ground. This method is used for oil spills but can allow for water by varying the liquid properties (primarily viscosity and permeability).

Equation 1 Grimaz et al. (2007)

$$A_{pool} \cong 2.3782 \frac{Q^{4/5}}{(k_i k_r)^{1/5}} \quad (1)$$

Where: A_{pool} *is the area of the pool of liquid on the surface [m²]; Q is the total amount of liquid released [m³];* k_i *is the intrinsic permeability of soil [m²];* k_r*, is the relative permeability of the liquid [-].*

The values of k_r, which vary with different grades of water saturation of soil, are shown in **Table 3-1**. For the conservative nature of this assessment, a k_r value of 0.3 will be assumed.

Table 3-2 provides the intrinsic permeability values used for sand and clay soil profiles. Sand and clay were chosen as these represent the extremes of potential infiltration and therefore bound the conditions observed in soils within the Area of Interest.

Table 3-1 Relative Permeability k_r, for Different Scenarios of Accidental Release

Soil situation	k_r
Dry - long time without rainfall in warm regions and in hot seasons	1
Slightly wet - long time without rainfall in other regions or seasons	0.9
Very wet - from 2 hours to 2 days after strong rainfall	0.3
Completely saturated - during strong rainfall with ponds on surface	0

Table 3-2 Values of Intrinsic Permeability and Kinematic Viscosity for Sand and Clay

Soil situation	Soil type	k_i
k_i = intrinsic permeability of soil (m^2)	Sand	1.00E-08
	Clay	1.00E-13

3.2 Infiltration into Unsaturated Zone

The spilt fluid will not only tend to spread out over the surface of the soil and evaporate but will also penetrate into the ground (unless it is impermeable). Infiltration to the unsaturated zone, and in particular infiltration capacity and time for ponding to occur, can be determined using the infiltration equation of Green and Ampt (1911).

The infiltration rate actually experienced in a given soil depends on the amount and distribution of soil moisture and on the availability of water at the surface with a maximum rate at which the soil in a given condition can absorb water. This upper limit is called the infiltration capacity, f_c, and is a limitation on the rate at which water can move into the ground. If surface water input is less than

infiltration capacity, the infiltration rate will be equal to the surface water input rate (w). If irrigation (analogous to a release) intensity exceeds the ability of the soil to absorb moisture, infiltration occurs at the infiltration capacity rate until the soil is saturated and ponding and associated runoff occurs. Infiltration capacity declines over time until a steady state is reached.

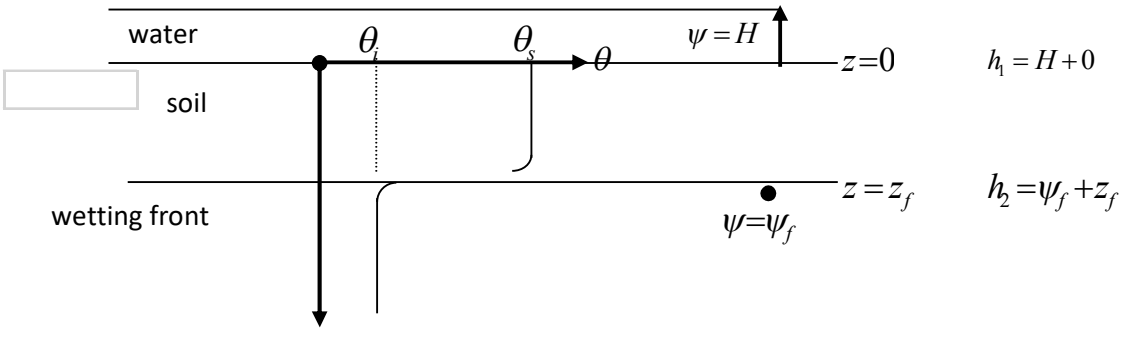
Several processes combine to reduce the infiltration capacity. The filling of fine pores with water reduces capillary forces drawing water into pores reducing the storage potential of the soil. Clay swells as it becomes wetter, and the size of pores is reduced. Coarse-textured soils such as sands have large pores which water can easily drain, while the fine pores in clays retard drainage. If the soil particles are held together in aggregates by organic matter or a small amount of clay, the soil will have a loose, friable structure that will allow rapid infiltration and drainage.

The calculation of infiltration at a point combines the physical conservation of mass (water) principle expressed through the continuity equation with quantification of unsaturated flow through soils, expressed by Darcy's equation. The downward hydraulic gradient inducing infiltration is from a combination of the effect of gravity, quantified by the elevation head, and capillary surface tension forces, quantified by the pressure head (negative due to suction) being lower at depth due to lower moisture content. If the water input rate is greater than the saturated hydraulic conductivity (i.e., w is greater than K_{sat}), at some point in time the water content at the surface will reach saturation. At this time, the infiltration capacity drops below the surface water input rate and runoff is generated. This time is referred to as the ponding time. After ponding occurs, water continues to infiltrate and a zone of saturation begins to propagate downward into the soil as the wetting front. After ponding, the infiltration rate is less than the water input rate and the excess water accumulates at the surface and becomes infiltration excess runoff. As time progresses and the depth of the zone of saturation increases, the contribution of the suction head to the gradient inducing infiltration is reduced, so infiltration capacity is reduced. Once the soil profile is completely saturated no further water can infiltrate.

3.2.1 Green and Ampt Infiltration Model

The Green and Ampt (1911) model (Equation 2) is an approximation of the infiltration process described above and was utilised to assess infiltration capacity and time for ponding for various soils.

Equation 2 Green and Ampt (1911)



$$q = -K_s \frac{dh}{dz} = -K_s \frac{h_2 - h_1}{z_2 - z_1} = -K_s \frac{(\psi_f + z_f) - (H + 0)}{z_f - 0} = -K_s \frac{\psi_f + z_f - H}{z_f} \qquad (2)$$

Where: *H = the depth of ponding, cm; Ks = saturated hydraulic conductivity (cm/s); q = flux at the surface (cm/h) and is negative; f = suction at wetting front (negative pressure head);* θ_i *= initial moisture content (dimensionless); and* θ_s *= saturated moisture content (dimensionless).*
The following assumptions are implicit in the Green-Ampt equation:

1. As water infiltrates, the wetting front advances at the same rate with depth, which produces a well-defined wetting front.
2. The volumetric water content remains constant above and below the wetting front as it advances.
3. The soil-water suction immediately below the wetting front remains constant with both time and location as the wetting front advances.

3.2.2 Darcy Infiltration Model

Once the soil has become permanently saturated (i.e., established) from a constant head driving behind the wetting front or when the Green and Ampt *flux (q) becomes constant*, Darcy's Law can be applied to determine the rate at which water can infiltrate vertically. This is shown in Equation 3.

$$qD = \frac{-K_{h,v}\frac{\Delta h}{\Delta l}}{n} \qquad (3)$$

Where: *qD = specific discharge of groundwater or Darcy Flux (m/day); Kh,v = average hydraulic conductivity (vertical [Kv] or horizontal [Kh]) of the saturated sediment (m/day);* $\Delta h / \Delta l$ *= hydraulic gradient driving the fluid (-); and* η *= effective porosity (-).*

3.3 Leaching within the Unsaturated Zone

3.3.1 VLEACH Unsaturated Zone Leaching Model

VLEACH is a 1-D finite difference vadose zone leaching model developed for the United States Environmental Protection Agency Office of Research and Development by CH2M Hill (CH2M Hill, 1990). VLEACH can simulate the behaviour of constituents in three phases: liquid phase, vapour phase and solid (sorption) phase.

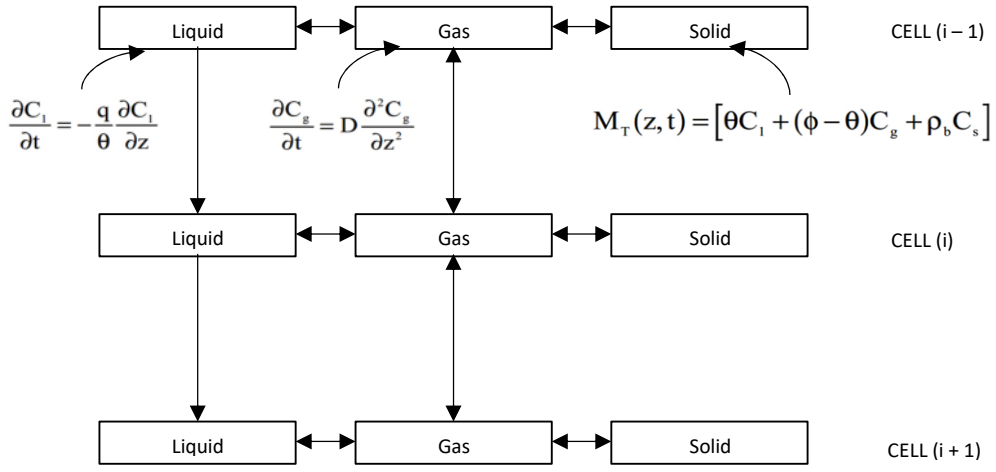


Figure 3-2 VLEACH process diagram

4 Analytical Assessment (Approach & Results)

This section presents the results of the assessment outlined in **Section 1.2**, and the methodology (described in **Section 3.1** and **Section 3.2**) for determining:

- Lateral spreading/overland flow (**Section 4.1**);
- Infiltration into unsaturated zone (**Section 4.2**);
- Infiltration rates under saturated flow conditions (**Section 4.3**); and
- VLEACH model results for each chemical constituent (**Section** Error! Reference source not found.).

4.1 Overland Flow

4.1.1 Overland Flow on Flat Surfaces

To assess the unmitigated risks from the improbable scenario where some fluids were to overflow the bunded area, a range of release scenarios are considered comprising:

1. Smaller release volumes of 1,000 L and 100,000 L, which would reflect small scale releases, and
2. An improbable release out of the bunded area (1,000,000 L).

Section 2 presents a summary of the recorded shallow lithology in each EP based on petroleum drillholes, licenced groundwater extraction wells and stock and domestic supply wells. For modelling purposes, the shallow stratigraphy in each EP has been simplified. It is noted that this simplification allows for a more conservative evaluation of infiltration, as most surficial sediments in the Areas of Interest are composed of either natural clays or clays derived from weathering of the host rock.

Table 4-1 presents the simplified stratigraphy in each EP adopted for modelling and model input parameters are provided in **Table 4-2**. It is noted that the shallow stratigraphy across the Areas of Interest are considered to be laterally equivalent and/or comprise similar hydraulic properties; these can be grouped into two main categories;

1) Low permeability formations including the Anthony Lagoon Beds, Chambers River Formation, Tomkinson Creek Beds, Kyalla Member and Atrium Plateau Volcanics
2) Higher permeability formations including the Bukalorkmi Sandstone, Gum Ridge Limestone, Tindall Limestone and Weaner Sandstone

For the purposes of assessing surface water pooling, soil properties reflective of a clay and more permeable sandier soils have been applied to Equation 1. These parameters are presented in **Table 3-1** and **Table 3-2.**

Table 4-1 Simplified Stratigraphy -Top 50 m Profile

Exploration Permit	Lithology	Hydrogeological Unit
EP167	Clay and Limestone	Tindall Limestone
EP168	Clay and Limestone	Tindall Limestone
EP169 (central and east)	Clay and Limestone	Anthony Lagoon Beds/Gum Ridge Formation
EP169 (west)	Clay and Sandstone	Tomkinson Creek Beds
EP184	Siltstone/Mudstone/Sandstone	Kyalla Member/Bukalorkmi
EP187	Clay and Limestone	Gum Ridge Formation/Anthony Lagoon Beds
EP198 (central and east)	Clay and Basalt	Antrim Plateau Volcanics
EP198 (west)	Dolomite/Siltstone	Weaner Sandstone/Bynoe Formation
EP305	Clay and Basalt	Antrim Plateau Volcanics

Table 4-2 Modelling Input Parameters

Parameter	Anthony Lagoon Beds / Chambers River Formation / Tomkinson Creek Beds / Kyalla Member / Atrium Plateau Volcanics	Bukalorkmi Sandstone / Gum Ridge Limestone / Tindall Limestone / Weaner Sandstone	Literature Source
Exploration Permit	EP169 (west), EP184 EP198 (central and east), EP305	EP167, EP168, EP169 (central and east), EP187	
Porosity	0.482*	0.4**	* Dingman, 1994 **Knapton, 2006
Hydraulic Conductivity (K_{sat}) (m/d)	$8.6x10^{-4}$	0.864	Freeze, R. A., & Cherry, J. A. (1979).
Air-Entry Tension (cm)	40.5	12.1	Dingman, 1994
Saturated Tension (cm)	30.78	9.2	Dingman, 1994
Intrinsic permeability (m^2)	$1x10^{-13}$	$1x10^{-8}$	Dingman, 1994

Dingman, S.L. 1994. Physical Hydrology Edition 5, Macmillan Publishing Company, 1994 ISBN 002329745X, 9780023297458 575 pages

Freeze, R.A. and Cherry, J.A. 1979. Groundwater. Prentice-Hall, Inc., Englewood Cliffs.

Knapton. 2006. Regional Groundwater Modelling of the Cambrian Limestone Aquifer System of the Wiso Basin, Georgina Basin and Daly Basin. Technical Report No. 29/2006A Department of Natural Resources, Environment & The Arts, Alice Springs.

Without the inclusion of bunding, a catastrophic release (1ML) could impact an area of up to 30.8 ha. In the event of smaller scale release 1,000 L or 100,000 L and prior to any bunds being established, these impacts would be highly localised to between 0.4 ha and 4.7 ha (effectively the equivalent area of the well pad).



Table 4-3 Model Results - Pooled Water Area

Stratigraphic Unit	Volume Released (L)	Volume Released (m^3)	Area (m^2)	Radius (m)	Comment
Anthony Lagoon Beds / Chambers River Formation / Tomkinson Creek Beds / Kyalla Member / Atrium Plateau Volcanics	1,000	1	1204.5	19.6	Releases of 1 to 100m^3 improbable to over topping bunding walls.
	100,000	100	47953.9	123.5	
	1,000,000	1,000	308568.8	310.3	
Bukalorkmi Sandstone / Gum Ridge Limestone / Tindall Limestone / Weaner Sandstone	1,000	1	120.4	6.2	Releases of 1 to 100m^3 improbable to over topping bunding walls.
	100,000	100	4795.4	39.1	
	1,000,000	1,000	30256.9	98.1	

4.2 Green and Ampt Infiltration Model

In addition to potential overland flow, infiltration into the sub-surface would occur. In the case of releases which are not contained within the bunded area, the infiltration rate would be slow due to the limited head of fluids within the release area, while in the bunded area the retention of release fluids would provide a higher head as liquids could be present up to the height of the surrounding walls.

The results of the Green and Ampt Infiltration equation are discussed below and shown in **Figure 4-1**.

Recalling from **Section 2** and **Section 4.1.1** above, there are two distinct hydrogeological units (siltstone/clay/basalt and limestone/permeable sandstone) that extend across the Areas of Interest. The assessment therefore is based upon the time to infiltrate through both these formations.

Assuming the sub-surface is similar to the lower permeable units as defined in **Table 4-1** and **Table 4-2**, the results indicate that the ground would become quickly saturated (the infiltration capacity of the soils are exceeded) and any spill will take approximately 158 years to move through the initial 50 m. This is based on a saturated hydraulic conductivity of a siltstone/clay/basalt (K = 0.000001 cm/s [0.00086 m/d]). As a comparison, if a limestone or permeable sandstone with an average saturated hydraulic conductivity of a fractured unit (K = 0.001 cm/s [0.864 m/d]) was present at surface, this travel time is greatly reduced to 115 days.

4.3 Darcy Infiltration Model

The results of the Darcy infiltration modelling are discussed below and shown in **Figure 4-1**. Adopting the same assumptions as presented in **Section 4.2**, (i.e., the sub-surface is similar to the units described in **Table 4-1** and hydraulic properties defined in **Table 4-2**) and that the water is available in the surface to act as a driving head (i.e., a consistent leak), the results indicate water will take approximately 80 years to move through the initial 50 m (siltstone/clay/basalt) or approximately 30 days if the sub-surface was equivalent to a limestone or permeable sandstone.

It should be noted that this evaluation is highly conservative as it assumes the sub-surface is completely saturated and has a constant driving head. However, in reality the driving head will be removed, either by evaporation or remediation, well before the predicted travel time is reached.

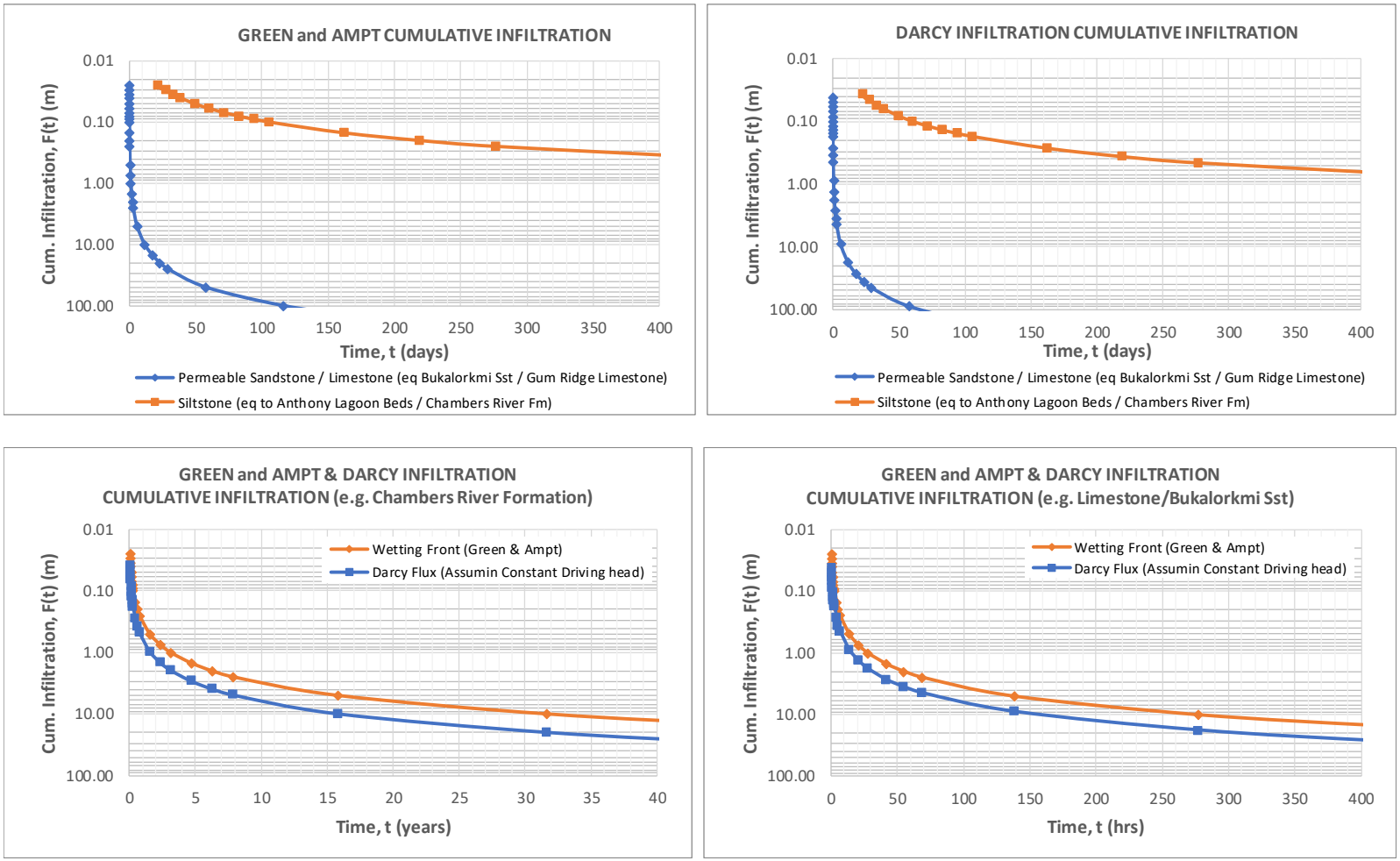


Figure 4-1 Results of the Green-Ampt Analytical Model for Limestone and Siltstone

Siltstone equivalent to the Anthony Lagoon Beds / Chambers River Formation / Tomkinson Creek Beds / Kyalla Member / Atrium Plateau Volcanics
Permeable sandstone equivalent to the Bukalorkmi Sandstone / Gum Ridge Limestone / Tindall Limestone / Weaner Sandstone

4.4 VLEACH Model

Based on the chemistry (e.g., drilling muds), leaching assessments were conducted on a scenario where drilling muds were stabilised (by blending with native soils to manage residual moisture) and compacted and placed below ground surface. Typically, the drilling muds are buried 1 to 2 m below ground surface to ensure the materials are below the rooting depth of crops and plants, and the area is graded to prevent ponding and preferential infiltration of water. The blend of drilling muds and cuttings produces a low permeability material (between $1x10^{-8}$ m/sec and $1x10^{-10}$ m/sec.) with a high cation exchange capacity (CEC). This results in metals and metalloids being strongly bound within the muds and the mud and cuttings exhibiting very low permeabilities. The conceptualisation of leaching from the buried drillings muds is provided in **Figure 4-2**.

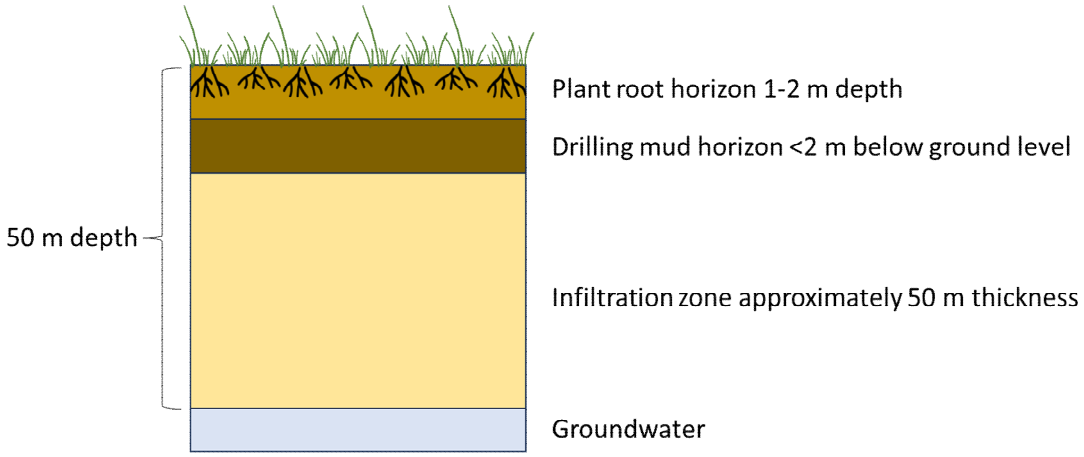


Figure 4-2 Conceptualisation of Drilling Mud Leaching

For the purposes of the modelling, organic compounds (methanol and glutaraldehyde) and chloride (from sodium chloride) migration were assessed through the soil profile. Methanol and glutaraldehyde are water soluble (unlike insoluble polymers and starch) and are subject to attenuation in the sub-surface through biodegradation and sorption. Chloride was used to evaluate conservative migration with no attenuation, i.e. no degradation or sorption.

The drilling mud chemistry is provided in **Table 4-4** and the properties of the modelled chemical constituents are presented in **Table 4-5**.

Table 4-4 Selected Drilling Mud Chemistry

Chemical Name	Concentration in Drilling Mud Solids (µg/kg)
Glutaraldehyde	300,000
Methanol	3,000
Chloride[1]	27,656,932

[1] Calculated from a sodium chloride concentration in drilling mud solids of 45,600,000 µg/kg

Table 4-5 Constituent Properties

Chemical Name	Concentration in drilling mud (mg/L)	Organic Distribution Coefficient[2] (mL/g)	Henry's Law Constant[1] (atm-m^3/mol)	Water Solubility[1] (mg/L)	Free Air Diffusion Coefficient[1] (m^2/day)
Methanol	3	0.014	0.0001937	1,000,000	1.296
Glutaraldehyde	300	0.07	0.0000108	85,500,000	0.096
Chloride	18,135[3]	1	1E-20	360,000[4]	1E-20

Although the drilling muds are conceptualised as stabilised with native soils, the unblended drilling mud concentrations have been used in the modelling.

The vadose zone is simulated as a homogeneous, isotropic horizon with the same physical properties throughout the layer. The depth to groundwater is estimated as 50 m bgl.

The behaviour of three constituents were simulated. An example of the input parameters for chloride is provided in **Table 4-6**.

Table 4-6 Chloride VLEACH Input Parameters

Input Parameter	Value	Unit
Number of polygons	1	-
Timestep	1	years
Simulation time	50	years
Output time interval	1	years
Profile time interval	1	years
K_{oc}	1	mL/g
Henrys constant	$1x10^{-20}$	dimensionless
Water solubility	218,284	mg/L
Free air diffusion coefficient	$1x10^{-20}$	m^2/day
Area	10.76	$feet^2$
Vertical cell dimension	164.05	feet
Initial Recharge rate	5	feet/year
Dry bulk density	1.6	g/cm^3
Effective porosity	0.4	dimensionless
Initial Volumetric water content	0.17	%
Soil organic carbon content	0.001	fraction
Concentration of recharge water	18,135	mg/L
Upper boundary condition for vapour	0	mg/L
Lower boundary condition for vapour	0	mg/L
Cell number	50	-
Total Plot time	50	years
Initial contaminant concentration	27,656,932	µg/kg

The VLEACH model results for each chemical constituent are presented in **Figure 4-3** and **Figure 4-4**

[2] GSI Chemical Properties Database (http://www.gsi-net.com/en/publications/gsi-chemical-database.html)
[3] Calculated from sodium chloride concentration in drilling mud fluids of 29,900 mg/L
[4] http://srdata.nist.gov/solubility/index.aspx

The results indicate that the organic constituents (methanol and glutaraldehyde) take approximately 100 years to move 20 m through the vadose zone sub-surface. Concentrations are very low once below 20 m depth.

Chloride has been simulated as a conservative species. Two input parameters were varied, volumetric water content (VWC) and recharge rate. The VWC affects the migration through the vadose zone by diluting the constituent and lowering the mass that could potentially reach the water table. The recharge rate increases the constituent migration and reduces the time taken to reach steady state conditions. The values of 17% VWC and a recharge rate between 0.1 and 0.5 m/yr are considered to be conservative values to represent the entire vadose zone and the vadose zone is expected to be drier especially at shallow depths. The time taken to reach steady-state conditions is therefore likely to be in excess of 20 to 50 yrs. The steady state concentration of chloride that could potentially discharge to groundwater is estimated as 29 mg/L[5] which is below the aesthetic criteria for drinking water.

[5] Calculated using a steady state chloride concentration of 18 ug/kg and a bulk density of 1.6 g/cm^3

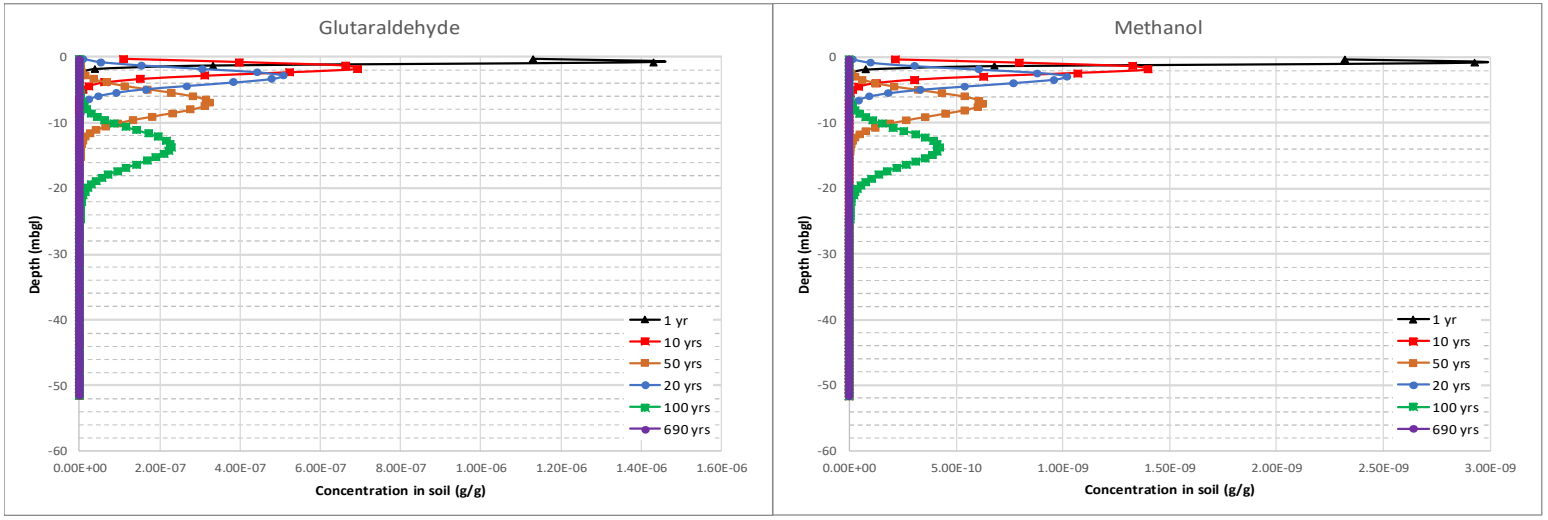


Figure 4-3 VLEACH Results – Organic Constituents

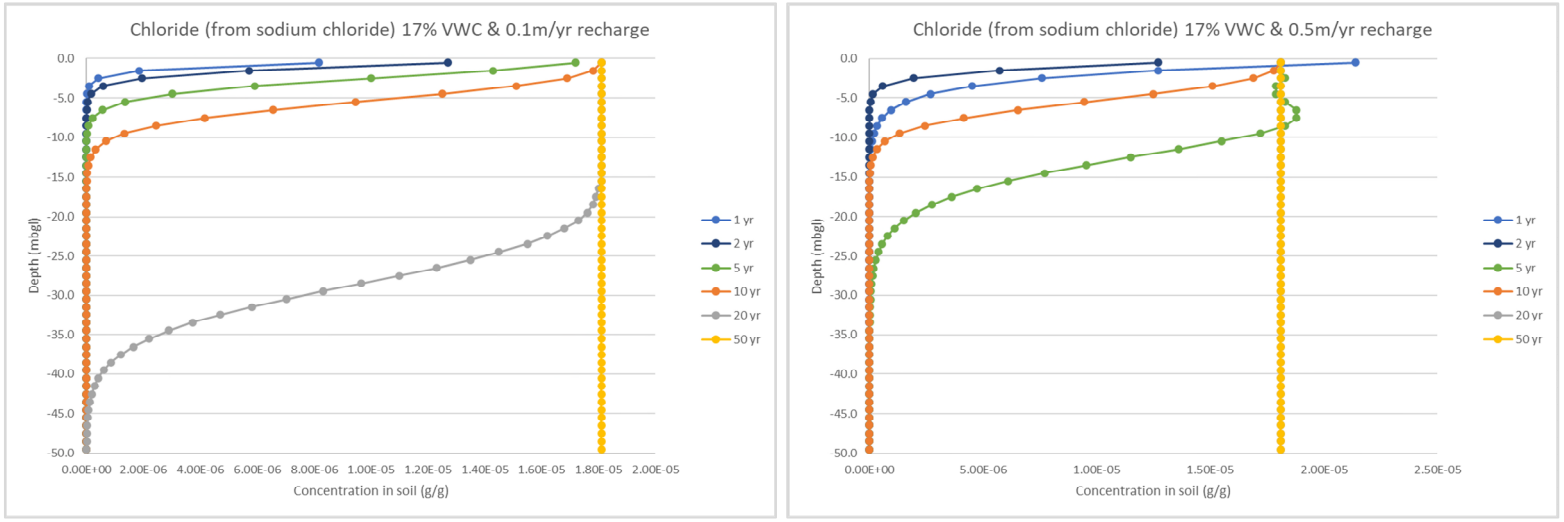


Figure 4-4 VLEACH Results – Chloride

5 Discussion

The results of this assessment present a very conservative estimate of the potential impacts to surface environmental receptors and groundwater. Its conservatism is inherent in the assumption that some of the scenarios considered that no risk mitigation measures were adopted and that the water releases were catastrophic.

In the context of smaller scale releases outside of the bunded area, this assessment indicates that spills of 1,000 L and 100,000 L, would only migrate a radial distance of 6 m and 124 m respectively, with the maximum area of impact being 4.7 ha. This also assumes flow over relatively impermeable siltstone.

In the context of potential impact to groundwater via infiltration, modelling using both Green and Ampt (1911) and Darcy's equations (1856) (to assess unsaturated and saturated soils) has been conducted based on highly conservative assumptions. It has been determined that water would take 158 years (through siltstone/clay/basalt) and 115 days if the surficial sequence is consistent with limestone/permeable sandstone to reach groundwater at a depth of approximately 50 m below ground level. However, the modelling does not consider the capacity of the formation to retain water. In this context and based on the finite volume of water in the compound, it is not anticipated that a single release would infiltrate to groundwater. Assuming the ground remained saturated (via an undetected consistent leak), water will take approximately 80 years to move through the initial 50 m (siltstone/clay/basalt) or approximately 30 days if the sub-surface was equivalent to a limestone or permeable sandstone.

The results of the VLEACH modelling indicate that the modelled organic constituents (methanol and glutaraldehyde) take a very long time to move through the sub-surface and organic concentrations are likely to be less than 1 x 10^{-7} g/g once below 20 metres depth. Note that both methanol and glutaraldehyde are readily biodegradable, and it is likely that these constituents would completely decompose within the predicted 100 years that it would take infiltration to reach 20 m depth[6]

Chloride concentrations are estimated to take a minimum of 20 years to reach steady state concentrations under a conservative scenario. The steady state concentration of chloride that could potentially discharge to groundwater is estimated as 29 mg/L[7] which is below the aesthetic criteria for drinking water. Further, assuming that there actually is a complete infiltration pathway that would allow chloride to reach groundwater at these concentrations, these concentrations would occur over a very localised area, and further dilution would readily occur in groundwater.

[6] Half-lives of glutaraldehyde and methanol vary depending on the biodegradation environment, but are on the order of days. Half-lives for glutaraldehyde have been measured at 7.7 and 10.6 hours in anaerobic and aerobic aquatic environment metabolism tests, respectively. Half-lives for methanol have been measured at approximately 5 days based on aerobic and anaerobic soil tests. (EHS Support, 2023)

[7] Calculated using a steady state chloride concentration of 18 ug/kg and a bulk density of 1.6 g/cm^3

6 Limitations

EHS Support Pty Ltd (EHS Support) has prepared this report in accordance with the usual care and thoroughness of the consulting profession for the use of inGauge and only those third parties who have been authorised in writing by EHS Support to rely on the report. It is based on generally accepted practices and standards at the time it was prepared. No other warranty, expressed or implied, is made as to the professional advice included in this report. It is prepared in accordance with the scope of work and for the purpose outlined in the Proposal dated 20 September 2023.

The methodology adopted and sources of information used by EHS Support are outlined in this report. EHS Support has made no independent verification of this information beyond the agreed scope of works and EHS Support assumes no responsibility for any inaccuracies or omissions. No indications were found during our investigations that information contained in this report as provided to EHS Support was false.

This report was prepared in December 2021 and is based on the information reviewed at the time of preparation. EHS Support disclaims responsibility for any changes that may have occurred after this time.

This report should be read in full. No responsibility is accepted for use of any part of this report in any other context or for any other purpose or by third parties. This report does not purport to give legal advice. Legal advice can only be given by qualified legal practitioners.

This report contains information obtained by inspection, sampling, testing or other means of investigation. This information is directly relevant only to the points in the ground where they were obtained at the time of the assessment. The borehole logs indicate the inferred ground conditions only at the specific locations tested. The precision with which conditions are indicated depends largely on the frequency and method of sampling, and the uniformity of conditions as constrained by the project budget limitations. The behaviour of groundwater and some aspects of contaminants in soil and groundwater are complex. Our conclusions are based upon the analytical data presented in this report and our experience. Future advances in regard to the understanding of chemicals and their behaviour, and changes in regulations affecting their management, could impact on our conclusions and recommendations regarding their potential presence on this site.

Where conditions encountered at the site are subsequently found to differ significantly from those anticipated in this report, EHS Support must be notified of any such findings and be provided with an opportunity to review the recommendations of this report.

Whilst to the best of our knowledge information contained in this report is accurate at the date of issue, sub-surface conditions, including groundwater levels can change in a limited time. Therefore, this document and the information contained herein should only be regarded as valid at the time of the investigation unless otherwise explicitly stated in this report.

7 References

Close D.I., Baruch E.T., Altmann C.M., Cote A.J., Mohinudeen F.M., Richards B. and Stonier S. 2016. Unconventional gas potential in Proterozoic source rocks: Exploring the Beetaloo Sub-basin: in Annual Geoscience Exploration Seminar (AGES) Proceedings, Alice Springs, Northern Territory 15–16 March. Northern Territory Geological Survey, Darwin, 91–94.

CH2M Hill (1990) VLEACH A one-dimensional finite difference vadose zone leaching model. Prepared for USEPA, August 1990

Darcy, H. (1856). Les fontaines publiques de la ville de Dijon. Paris: Dalmont.

Dingman, S.L. 1994. Physical Hydrology Edition 5, Macmillan Publishing Company, 1994 ISBN 002329745X, 9780023297458 575 pages

EHS Support. 2023. Human Health and Environmental Risk Assessment for Carpentaria Gas Project – Imperial Oil & Gas and Imperial Oil and Gas A Northern Territory Tenement. Rev 2.

Esteves, M., X. Faucher, S. Galle, and M. Vauclin. 2000. “Overland flow and infiltration modeling for small plots during steady rain: Numerical results versus observed values.” Journal of Hydrology 228:265-282.

Evans TJ, Radke BM, Martinez J, Buchanan S, Cook SB, Raiber M, Ransley TR, Lai ÉCS, Skeers N, Woods M, Evenden C, Cassel R and Dunn B (2020) Hydrogeology of the Beetaloo GBA region. Technical appendix for the Geological and Bioregional Assessment: Stage 2. Department of the Environment and Energy, Bureau of Meteorology, CSIRO and Geoscience Australia, Australia.

Freeze, R.A. and Cherry, J.A. 1979. Groundwater. Prentice-Hall, Inc., Englewood Cliffs.

Fulton S. and Knapton A. 2015. Beetaloo Basin Hydrogeological Assessment.

Grimaz, S., Allen, S., Steward, J. and Dolcetti, G. 2007. “Predictive evaluation of the extent of the surface spreading for the case of accidental spillage of oil on ground”. Selected Paper IcheaP8, AIDIC Conference series, Vol. 8, pp. 151-160.

Green, W.H. and G. Ampt. 1911. Studies of Soil Physics, Part I – The Flow of Air and Water Through Soils. J. Ag. Sci. 4:1-24.

inGauge Energy Australia (inGauge). 2020. Environment Management Plan Imperial 2020 Hydraulic Fracturing Program NT Exploration Permit (EP) 187.

Knapton. 2006. Regional Groundwater Modelling of the Cambrian Limestone Aquifer System of the Wiso Basin, Georgina Basin and Daly Basin. Technical Report No. 29/2006A Department of Natural Resources, Environment & The Arts, Alice Springs.

Kruse P.D., Dunster J.N. and Munson T.J. 2013. Chapter 28: Georgina Basin: in Ahmad M and Munson TJ (compilers). ‘Geology and mineral resources of the Northern Territory’. Northern Territory Geological Survey, Special Publication 5.

Matthews I. 2008. Minyeri – Regional groundwater investigation and expansion of exisiting borefield. Territory Groundwater Services, Darwin NT.

NT DIPE (1992) Helen Springs 1:250,000 Hydrogeological Map

NT DIPE (1997) Victoria River Downs 1:250,000 Hydrogeological Map

Woolhiser, A. and J. A. Liggett. 1967. Unsteady, one-dimensional flow over a plane— The rising hydrograph. Water Resources Research, 3(3):753–771, 1967. ISSN 0043-1397. doi: 10.1029/WR003i003p00753.

Yin Foo D. and Matthews, I. 2000. Hydrogeology of the Sturt Plateau. Department of Infrastructure and Planning and Environment. Northern Territory Government. Report 17/2000D.

Zaar. 2009. Water Resources of the Roper River Region. Report 16/2009D. A report prepared for the Northern Territory Government. https://denr.nt.gov.au/__data/assets/pdf_file/0006/438009/Gulf-Water-Study.pdf

Appendix C Risk Dossiers

Appendix C.1 March 2020 Risk Dossiers

ETHYL HEXANOL
[2-ETHYLHEXANOL]

This dossier on ethyl hexanol (designated in this dossier as 2-ethylhexanol) presents the most critical studies pertinent to the risk assessment of ethyl hexanol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Ethylhexan-1-ol

CAS RN: 104-76-7

Molecular formula: $C_8H_{18}O$

Molecular weight: 130.23

Synonyms: 2-Ethylhexanol, 2-ethylhexan-1-ol, 2-ethyl-*n*-hexyl alcohol

SMILES: CCCCC(CC)CO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of 2-Ethylhexanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear and colourless liquid	2	ECHA
Melting Point	-89°C	2	ECHA
Boiling Point	184°C; 186°C	2	ECHA
Density	0.833 g/cm^3 @ 20°C	2	ECHA
Vapor Pressure	93 Pa @ 20°C 120 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	2.9	2	ECHA
Water Solubility	0.9 g/L	2	ECHA

Property	Value	Klimisch score	Reference
Flash Point	77°C; 75°C @ 1013 hPa	2	ECHA
Auto flammability	280°C	1	ECHA
Viscosity	9.7 mPa s @ 20°C 4.3 mPa s @ 40°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

2-Ethylhexanol is readily biodegradable. It is not expected to bioaccumulate. 2-Ethylhexanol has a low tendency to bind to soil or sediment.

B. Biodegradation

2-Ethylhexanol was considered readily biodegradable in an OECD TG 301C test. After two weeks, degradation was 79 to 99.9% measured by O_2 consumption, 100% degradation measured by TOC removal, and 100% degradation as determined by test material analysis (ECHA) [Kl score = 1]. 2-Ethylhexanol was inherently biodegradable in a Zahn-Wellens test (OECD TG 302B), with >95% degradation within five days (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for 2-ethylhexanol. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} value from log K_{ow} is 105.6 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 35.28 L/kg.

D. Bioaccumulation

No bioconcentration studies have been conducted on 2-ethylhexanol. Per calculations using EPISUITE™ (EPA, 2017), the log BCF via the Arnot-Gobas method for upper trophic level organisms is 1.543 (BCF = 34.88). Thus, 2-Ethylhexanol is not expected to bioaccumulate which is consistent with its experimental log K_{ow} of 2.9 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

2-Ethylhexanol has low acute toxicity by the oral route; virtually no acute toxicity by the dermal route; and has moderate acute toxicity by the inhalation route. It is a skin and eye irritant. No skin sensitisation studies on 2-ethylhexanol were located. Repeated exposure studies in rodents caused liver effects (*i.e.*, peroxisomal proliferation); these effects are not thought to

occur in humans. 2-ethylhexanol is not genotoxic. Lifetime oral studies in rats and mice showed no carcinogenic effects. 2-Ethylhexanol is not expected to have an effect on reproduction based on findings in animals from similar compounds. No developmental toxicity was seen in animals exposed to 2-ethylhexanol by the oral, dermal, or inhalation routes.

B. Acute Toxicity

The oral LD_{50} values in rats are; 2,047 mg/kg (Smyth et al., 1969); 3,290 mg/kg (Schmidt et al., 1973); and 3,730 mg/kg (Scala and Burtis, 1973). [Kl. scores = 2]

The 4-hour whole body inhalation LC_{50} in rats is >0.89 mg/L as vapor; no deaths were reported (ECHA). [Kl. score 2]

The dermal LD_{50} values in rats and rabbits are >3,000 and >2,600 mg/kg, respectively. There were no deaths in either study (ECHA). [Kl. score = 1 and 2, respectively]

C. Irritation

Application of 0.5 ml 2-ethylhexanol to the skin of rabbits for 4 hours under semi-occlusive conditions was severely irritating (ECHA). [Kl. score = 1]

Instillation of 0.1 ml 2-ethylhexanol into the eyes of rabbits was irritating. The mean of the 24, 48, and 72 hours scores were: 1.44 for corneal opacity; 0.89 for iridial lesions; 2.56 for conjunctival redness; and 0.78 for chemosis. The effects were fully reversible within 21 days (ECHA). [Kl. score = 1]

D. Sensitization

No studies are available.

E. Repeated Dose Toxicity

<u>Oral</u>
Male F344 rats were given in their feed 0 or 2% 2-ethylhexanol for three weeks. The objective of this study was to investigate the liver effects of 2-ethylhexanol on hepatic peroxisome proliferation and peroxisome enzymes. There were no significant treatment-related effects on body weight, but liver weights relative to body weights, catalase activity, liver carnitine acetyltransferase activity, and hepatic peroxisome proliferation (as determined by electron microscopy) were significantly increased. There was also a treatment-related decrease on serum levels of cholesterol and triglycerides. The LOAEL is 2% in the diet; a NOAEL was not established (Moody and Reddy, 1978). [Kl. score = 2]

Male and female F344 rats were dosed with 0, 25, 125, 250, or 500 mg/kg 2-ethylhexanol (in an aqueous suspension with an emulsifier) 5 days/week for 13 weeks. Body weights were decreased in the 500 mg/kg group (both sexes). Relative liver, kidney, and stomach weights were increased in the 250 and 500 mg/kg groups. Gross pathological examination showed forestomach lesions in the 500 mg/kg animals. Palmitoyl CoA oxidase activity was increased in

the livers of the 500 mg/kg animals (both sexes). The NOAEL for systemic toxicity is 125 mg/kg-day (Astill *et al.*, 1996a). [Kl score = 1]

Male and female B6C3F_1 mice were dosed with 0, 25, 125, 250, or 500 mg/kg 2-ethylhexanol (in an aqueous suspension with an emulsifier) 5 days/week for 13 weeks. Treatment-related effects included increased stomach weights (≥250 mg/kg) and increased liver weights (125 and 250 mg/kg). Treatment-related histopathological changes were limited to acanthosis (diffuse hypertrophy or thickening of the prickle cell layer) of the forestomach mucosa in the 500 mg/kg animals (both sexes). No increases in palmitoyl CoA oxidase activity were seen in the livers of male and female mice at any dose level. The NOAEL for systemic toxicity is 500 mg/kg-day (Astill *et al.*, 1996). [Kl. score = 1]

Male and female F344 rats were dosed by oral gavage with 0, 50, 150, or 500 mg/kg 2-ethylhexanol (in 0.0005% Cremophor EL, a polyoxyl-35 castor oil) 5 days/week for two years. A water control was also included in the study. There were no differences of biological importance between the vehicle control and a water control group. Reduced body weight gain occurred in the 150 and 500 mg/kg groups with an increased incidence of lethargy and unkemptness. There were dose-related increases in relative liver, stomach, brain, kidney, and testis weights at study termination. Mortality was significantly increased among the 500 mg/kg females, and there was marked aspiration-induced bronchopneumonia in the high-dose animals. Gross and histopathological non-neoplastic changes were similar between treated and control groups. The NOAEL is 50 mg/kg-day (Astrill *et al.*, 1996b). [Kl. score = 1]

Male and female B6C3F_1 mice were dosed by oral gavage with 0, 50, 200, or 750 mg/kg 2-ethylhexanol (in 0.0005% Cremophor EL, a polyoxyl-35 castor oil) 5 days/week for two years. A water control was also included in the study. There were no differences of biological importance between the vehicle control and a water control group that was also included in the study. All treatment-related effects occurred only in the 750 mg/kg animals (both sexes). Mortality was increased and body weight gain was reduced, and there was a slight increase in nonneoplastic focal hyperplasia in the forestomach. Relative liver and stomach weights occurred in the 750 mg/kg animals (both sexes). The NOAEL is 200 mg/kg-day (Astill *et al.*, 1996b). [Kl. score = 1]

Inhalation

Male and female Wistar rats were exposed by inhalation (whole body exposure) to 0, 15, 40, or 120 ppm 2-ethylhexanol 6 hours/day, 5 days/week for 13 weeks. No adverse effects including cyanide-insensitive palmitoyl CoA oxidation (a parameter for hepatic peroxisome proliferation) were observed. The NOAEC for this study is 120 ppm (ECHA). [Kl. score = 1]

Dermal

No adequately or reliable studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on 2-ethylhexanol are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on 2-Ethylhexanol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Mammalian cell gene mutation (CHO cells/HGPRT)	-	-	1	ECHA
Mammalian cell gene mutation (L5178Y mouse lymphoma cells)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	2	ECHA
Sister chromatid exchange (CHO cells)	-	-	2	ECHA

*+, positive; -, negative

In Vivo Studies

Male and female B6C3F_1 mice were given 456 mg/kg 2-ethylhexanol either as single intraperitoneal injection or two intraperitoneal injections on two consecutive days. There were no increases in micronuclei in the bone marrow polychromatic erythrocytes under either dosing regimen (ECHA). [Kl. score = 2]

G. Carcinogenicity

Oral

Male and female F344 rats were dosed by oral gavage with 0, 50, 150, or 500 mg/kg 2-ethylhexanol (in 0.0005% Cremophor EL, a polyoxyl-35 castor oil) 5 days/week for two years. A water control was also included in the study. There was no evidence of treatment-related neoplastic lesions in any of the exposed groups (Astill *et al.*, 1996b). [Kl. score = 1]

Male and female F344 rats were dosed by oral gavage with 0, 50, 200, or 750 mg/kg 2-ethylhexanol (in 0.0005% Cremophor EL, a polyoxyl-35 castor oil) 5 days/week for two years. A water control was also included in the study. There was a 12% incidence of hepatic basophilic foci and an 18% incidence of liver carcinomas in the 750 mg/kg male mice, which was not statistically significant compared with either control by Fisher's exact test. There was a 12% incidence of hepatic basophilic foci and a 10% incidence of liver carcinomas in the 750 mg/kg female mice, with was statistically significant compared with the vehicle but not with the water controls by Fisher's exact test. There was a weak trend in hepatocellular carcinoma incidence in the 750 mg/kg dose group, which may have been associated with toxicity. The time-adjusted incidence of hepatocellular carcinomas in male mice (18.8%) was within the historical control range at the testing facility (0–22%), but was outside the normal range of 0–2% for the female mice (13.1%) (Astill *et al.*, 1996b). [Kl. score = 1]

Inhalation
No studies are available.

H. Reproductive Toxicity

There are no reproductive toxicity studies on 2-ethylhexanol. However, a two-generation reproductive toxicity study has been conducted on the surrogate di (2-ethylhexyl) terephthalate at dietary doses of 0, 3,000, 6,000, or 10,000 ppm. Di (2-ethylhexyl) terephthalate is expected to be hydrolyzed in the body by carboxylesterases to 2-ethylhexanol and terephthalic acid. There were no adverse effects on reproductive parameters that included estrous cyclicity, gonadal functions, spermatogenic endpoints (motility, morphology, counts), mating behavior and performance, conception, gestation and parturition, and fertility in general. There were no adverse effects noted in the reproductive organs. Reduced postnatal pup weights (potentially related to maternal toxicity) were observed for both sexes in both generations in the 6,000 and 10,000 ppm dose groups. The NOAELs for reproductive and developmental toxicity are 10,000 ppm (the highest dose tested) and 3,000 ppm, respectively (Faber *et al.*, 2007; ECHA). [Kl. score = 2]

I. Developmental Toxicity

Oral
Pregnant female CD-1 mice were given 2-ethylhexanol in their diet by microencapsulation at 0, 0.009, 0.03, or 0.09% on gestational days 0 to 17. The calculated consumption of 2-ethylhexanol based on food consumption was 0, 17, 59, and 191 mg/kg-day, respectively. No maternal or developmental toxicity was observed. The NOAEL for maternal and developmental toxicity is 191 mg/kg-day (ECHA). [Kl. score = 1]

Inhalation
Pregnant female SD rats were exposed by inhalation to 0 or 850 mg/m^3 (approximately 190 ppm) 2-ethylhexanol 7 hours/day during gestational days 1 to 19. The inhalation exposure was considered to be the highest attainable vapor concentration. The only effect seen in the dams was a slight reduction in feed consumption. No developmental toxicity was observed. The NOAEC for maternal and developmental toxicity is 850 mg/m^3 (Nelson *et al.*, 1989; ECHA).

Dermal
Pregnant female F344 rats were given dermal applications of 0, 252, 840, or 2,520 mg/kg 2-ethylhexanol 6 hours/day during gestational days 6 to 15. The only effects seen in the dams were reduced body weight gain in the high-dose group and local skin irritation in the mid- and high-dose groups. No developmental toxicity was observed. The NOAELs for maternal (systemic) and developmental toxicity were 840 and 2,520 mg/kg-day, respectively (Tyl *et al.*, 1992).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for 2-ethylhexanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Two-year chronic studies have been conducted in rats and mice given oral gavage doses of 2-ethylhexanol. The lowest NOAEL from these studies is 50 mg/kg-day, based on reduced body weight and clinical signs in rats dosed with 150 and 500 mg/kg-day 2-ethylhexanol. The NOAEL of 50 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.75 mg/L

B. Cancer

2-Ethylhexanol was not carcinogenic to rats or mice in chronic oral studies. Therefore, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2-Ethylhexanol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2-Ethylhexanol is moderately toxic to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on 2-ethylhexanol.

Table 3: Acute Aquatic Toxicity Studies on 2-Ethylhexanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Fathead minnow	96-h LC_{50}	28.2	1	ECHA
Golden Orfe	96-h LC_{50}	17.1	1	ECHA
Daphnia magna	48-h EC_{50}	39	2	ECHA
Scenedesmus subspicatus	72-h EC_{50} EC_{10}	11.5 (biomass) 16.6 (growth rate) 3.2 (biomass) 5.3 (growth rate)	2	ECHA

Chronic Studies
The 72-hour EC_{10} from an algal study using *Scenedesmus subspicatus* was 3.2 and 5.3 mg/L, based on biomass and growth rate, respectively (ECHA). [Kl. score = 2]

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for 2-ethylhexanol follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (17.1 mg/L), invertebrates (39 mg/L), and plants (11.5 mg/L). On the basis that the data

consists of short-term studies from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported E(L)C_{50} value of 11.5 mg/L for algae. The $PNEC_{aquatic}$ is 0.012 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.027 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (2.83/1280) \times 1000 \times 0.012$
$= 0.019$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 4.22/1000 \times 2400]$
$= 2.83$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 105.6 \times 0.04$
$= 4.22$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for 2-ethylhexanol calculated from EPISUITE™ using log K_{ow} is 105.6 L/kg .
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.017 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (2.11/1500) \times 1000 \times 0.012$
$= 0.017$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
= 105.6 x 0.02
= 2.11

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for 2-ethylhexanol calculated from EPISUITE™ using log K_{ow} is 105.6 L/kg .
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

2-Ethylhexanol is readily biodegradable; thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 2.9, 2-ethylhexanol does not meet the screening criteria for bioaccumulation.

The 72-hour EC_{10} from an algal study on 2-ethylhexanol is >0.1 mg/L. The acute E(L)C_{50} for 2-ethylhexanol in fish, invertebrates and algae are >1 mg/L. Thus, 2-ethylhexanol does not meet the screening criteria for toxicity.

Therefore, 2-ethylhexanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 4
Acute Toxicity Category 4 [inhalation]
Skin Irritant Category 2
Eye Irritant Category 2
STOT Single Exposure Category 3 [respiratory irritation]

[Aquatic Acute Category 3]

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation
Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion
Do not induce vomiting. Get medical attention immediately.

Notes to Physician
All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media
Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards
Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapors, or spray Avoid contact with skin, eye, and clothing. Eliminate all sources of ignition.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Keep away from heat, sparks, and flame. Avoid contact with eyes, skin, and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage
Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for 2-ethylhexanol.

Engineering Controls
Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment
Respiratory Protection:
If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection:
Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection:
Use protective clothing chemically resistant to the this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection:
Use chemical goggles.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

2-Ethylhexanol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Astill, B.D., Deckhardt, L., Gembardt, C., Gingell, R., Guest, D., Hodgson, J.R., Murphy, S.R., and Tyler, T.R. (1996a). Fundam. Appl. Toxicol. 29: 31-39.

Astill, B.D., Gingell, R., Guest, D., Hellwig, J., Hodgson, J.R., Kuettler, K., Mellert, W., Murphy, S.R., Sielken, Jr., R.L., and Tyler, T.R. (1996b). Oncogenicity testing of 2-ethylhexanol in Fischer 344 rats and B6C3F1 mice. Fundam. Appl. Toxicol. 31: 29-41.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Faber, W.D., Deyo, J.A., Stump, D.G., and Rubie, K. (2007). Two-generation reproduction study of di-2-ethylhexyl terephthalate in Crl:CD rats. Birth Defects Res. B Dev. Reprod. Toxicol. 80: 69-81.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Moody, D.E., and Reddy, J.K. (1978). Hepatic peroxisome (microbody) proliferation in rats fed plasticizers and related compounds. Toxicol. Appl. Pharmacol. 45: 497-504.

Nelson, B.K., Brightwell, W.S., Khan, A., Krieg, Jr., E.F., and Hoberman, A.M. (1989). Developmental toxicology evaluation of pentanol, hexanol, and 2-ethyl-1-hexanol. J. Am. Coll. Toxicol. 8: 405-410.

Scala, R.A., and Burtis, E.G. (1973). Acute toxicity of a homologous series of branched-chain primary alcohols. Am. Ind. Hyg. Assoc. J. 34: 493-499.\

Schmidt, P., Gohlke, R., and Rothe, R. (1973). Z. Ges. HYg. Grenzgeb. 19: 485-490.

Smyth, Jr., H.F., Carpenter, C.P., Weil, C.S., Pozzani, U., Striegel, J.A., and Nycum, J.S. (1969). Range-finding toxicity data: List VII. Am. Ind. Hyg. Assoc. J. 30: 470-476.

Tyl, R.W., Fisher, L.C., Kubna, M.F., Vrbanic, M.A., Gingell, R., Guest, D., Hodgson, J.R., Murphy, S.R., Tyler, T.R., and Astill, B.D. (1992). The developmental toxicity of 2-ethylhexanol applied dermally to pregnant Fischer 344 rats. Fundam. Appl. Toxicol. 19: 176-185.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ACETALDEHYDE
[ETHANAL]

This dossier on acetaldehyde presents the most critical studies pertinent to the risk assessment of acetaldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ethanal

CAS RN: 75-07-0

Molecular formula: C2H4O

Molecular weight: 44.05

Synonyms: Acetic aldehyde, ethyl aldehyde,

SMILES: CC=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Acetaldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless, pungent liquid	1	ECHA
Melting point	-123.5°C	2	ECHA
Boiling point	20.2°C	2	ECHA
Density	0.785 g/cm^3 @ 18°C	2	ECHA
Vapor pressure	120.2 kPa @ 25°C	2	ECHA
Partition coefficient (log	-0.13 (QSAR)	2	EPA, 2019

Property	Value	Klimisch score	Reference
K_{ow})			
Water solubility	Miscible	2	ECHA
Flash point	-40°C	2	ECHA
Auto flammability	175°C	2	ECHA
Flammability	4% Lower explosion limit, 60% upper explosion limit	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Acetaldehyde is readily biodegradable and not expected to bioaccumulate. Regarding the adsorption coefficient of acetaldehyde, "it is not possible to calculate log of this capacity factor or log Koc." (ECHA).

B. Biodegradation

Acetaldehyde is readily biodegradable. In an OECD 301 C (MITI-I) test, degradation was 80% (BOD demand) and 93% (TOC removal) after 14 days (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for acetaldehyde. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} is 3.219 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1 L/kg. Based on the Kow method employed in EPISUITE, Log Koc is 0.508 (EPA, 2019).

D. Bioaccumulation

There are no bioaccumulation studies on acetaldehyde. Acetaldehyde is not expected to bioaccumulate based on a log K_{ow} of -0.17 (EPA, 2019). Consistent with the low Kow, Log BCF using the Arnot-Gobas method for the upper trophic level is -0.033 (BCF = 0.9265) (EPA, 2019).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Acetaldehyde is moderately acutely toxic by the oral route and has low acute toxicity by inhalation and dermal routes. It is a skin, eye and respiratory tract irritant, but is not considered a sensitizer for skin. Based on the available data, the chemical is not considered to cause serious health effects from repeated oral or inhalation exposure; there are no data for dermal exposure. Acetaldehyde is considered genotoxic by National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Several studies for gene mutation, chromosomal damage and sister chromatid exchanges induced by acetaldehyde were reported. Although acetaldehyde is genotoxic in vitro, inducing gene mutations, clastogenic effects, and sister-chromatid exchanges (SCEs) in mammalian cells in the absence of exogenous metabolic activation, negative results were reported in adequate tests on Salmonella. There is indirect evidence from in vitro and in vivo studies to suggest that acetaldehyde can induce protein-DNA and DNA-DNA cross-links. However, ECHA does not classify acetaldehyde as genotoxic. There is limited evidence for carcinogenicity, but it is considered carcinogenic. Increased incidences of tumours have been observed in inhalation studies on rats and hamsters exposed to acetaldehyde. In rats, there were dose-related increases in nasal adenocarcinomas and squamous cell carcinomas (significant at all doses). However, in hamsters, increases in nasal and laryngeal carcinomas were non-significant. All concentrations of acetaldehyde administered in the studies induced chronic tissue damage in the respiratory tract. Acetaldehyde is not considered to cause reproductive or developmental harm.

B. Acute Toxicity

Oral

Based on the available data, acetaldehyde is considered to have moderate acute oral toxicity, warranting hazard classification (see Recommendation section). Median oral lethal dose (LD50) values in rats were between 660 and 1930 mg/kg bw. The oral LD50 value in mice was 1230 mg/kg bw (SCCS, 2012). According to this value acetaldehyde is harmful if swallowed. Nevertheless, the observations from the more relevant inhalation route indicate that the systemic toxicity of acetaldehyde is low and that effects other than systemic might have contributed to the lethality after oral exposure of rats. It is reasonable to follow the current EU legal classification that does not classify acetaldehyde as acutely toxic after oral exposure.

Dermal

The chemical was reported to have low acute toxicity via the dermal route (LD50 in rabbits of 3540 mg/kg bw) (SCCS, 2012) and greater than 5,000 mg/kg bw (RIFM, 1976). Overall, the dermal route is of minor importance due to the volatility of acetaldehyde at room temperature.

Inhalation

The chemical was reported to have low acute toxicity via inhalation (median lethal concentration (LC50) in rats has been calculated as 24,040 mg/m3 (13,300 ppm)) (REACH). A 4-hour inhalation toxicity study was conducted with exposure levels of

10,436 ppm, 12,673 ppm, 15,683 ppm and 16,801 ppm. The experimental study was similar to the method described in OECD Test Guideline (TG) 403. Clinical signs of toxicity reported included restlessness and labored respiration.

C. Irritation

Based on the available data, acetaldehyde is considered to be only slightly irritating to skin. The chemical was reported to cause slight skin irritation when tested in rabbits for 4 hours under occlusive conditions in a guideline (OECD TG 404) study (REACH). In a non-guideline study on rabbits, 500 mg of the chemical produced slight irritation of the skin. Nevertheless, according to literature (RIFM 2003) that was evaluated by the Scientific Committee on Cosmetic Products and non-Food Products Intended for Consumers, concentrations greater than 1% in solution are likely to be irritating to the human skin.

The irritating potential to human eyes at 500 ppm is reported from human exposure to acetaldehyde (Silverman, 1946). Furthermore, an irritating potential for the respiratory tract can be derived from several oral animal studies and human experience.

D. Sensitization

Based on the available data, the chemical is not considered to cause skin sensitisation. The chemical was not found to induce dermal sensitisation when tested according to OECD TG 406 (REACH). Several skin sensitisation studies were also considered by the SCCS who concluded there is limited evidence of skin sensitisation following exposure to the chemical (SCCS, 2012).

E. Repeated Dose Toxicity

<u>Oral</u>
Based on the available data, the chemical is not considered to cause serious health effects from repeated oral exposure.

In a 4-week drinking water study in rats, the no observed adverse effect level (NOAEL) of 125 mg/kg bw/day was reported (SCCS, 2012). At the higher dose (675 mg/kg bw/day), relative kidney weights were slightly increased in males, while urine production was decreased. The effects and variations in serum biochemistry were considered to be attributed to reduced water intake. Effects on liver function or histology were not reported.

<u>Dermal</u>
No data are available.

<u>Inhalation</u>

Based on the available data, the chemical is not considered to cause serious health effects from repeated inhalation exposure.

In a 4-week repeat dose inhalation toxicity study in male Wistar rats, the no observed adverse effect concentration (NOAEC) for the chemical was reported to be 270 mg/m3 (150 ppm) (REACH). At higher concentrations (900 mg/m3 (500 ppm)), degeneration of the olfactory epithelium was reported.

F. Genotoxicity

Based on the weight of evidence from the available in vitro and in vivo genotoxicity studies, the chemical is considered to be genotoxic, warranting hazard classification for this endpoint.

In Vitro Studies

The chemical did not exhibit mutagenic activity in Salmonella typhimurium with and without metabolic activation (REACH). The chemical was reported to induce chromosomal aberrations and micronuclei in SD rat primary skin fibroblasts (CERI, 2007). The chemical also induced sister chromatid exchanges in Chinese hamster ovary (CHO) cells, aneuploidy in embryonic diploid fibroblasts of Chinese hamster, and nondisjunction in *Aspergillus nidulans*. In human lymphocytes, dose-dependent gene mutation, sister chromatid exchange and chromosomal aberration were induced. The chemical induced DNA strand breaks and DNA cross-links in human lymphocytes, and DNA protein cross links in rat nasal mucosa cells. In addition, in a DNA binding study using calf thymus DNA, positive results were obtained. In a modified OECD TG 471 assay (a single test was performed with one plate per strain and concentration), the chemical induced chromosomal aberrations in human TK6 cells without metabolic activation at levels ³0.25 mM and was cytotoxic at 1 mM.

In Vivo Studies

The chemical induced sister chromatid exchanges in Chinese hamster and mouse bone marrow (CERI, 2007). Chromosomal aberrations were also reported in a study using rat embryo cells administered the chemical through the amnion. In studies using intraperitoneal administration, micronuclei were induced in rat bone marrow cells, rat peripheral lymphocytes and mouse bone marrow cells. Induced micronuclei or morphological abnormalities were not found in mouse spermatids.

Although effects were not seen in the single study examining germ calls, there is sufficient evidence to classify the chemical as possibly causing mutagenic effects.

G. Carcinogenicity

The chemical is classified as hazardous, with the risk phrase 'Limited evidence of carcinogenic effect' (Carc. Cat. 3; R40) in HSIS (Safe Work Australia). The available data support this classification.

The chemical is classified by the International Agency for Research on Cancer (IARC) as Group 2B (possibly carcinogenic to humans) based on sufficient evidence of carcinogenicity in experimental animals (IARC, 1999). The chemical produced tumours of the respiratory tract in rats and hamsters following inhalation exposure at concentrations as low as 750 ppm, particularly adenocarcinomas and squamous cell carcinomas of the nasal mucosa in rats and laryngeal carcinomas in hamsters.

Tumour formation at the site of exposure suggests a threshold (non-genotoxic) mechanism of carcinogenicity. The US EPA Integrated Risk Information System (IRIS) Chemical Assessment Summary for acetaldehyde calculated a quantitative cancer risk of 1:10 000 at an air concentration of 50 µg/m3 (equivalent to 28 ppb) (US EPA IRIS, 1988). In a subsequent report, IARC also classified the chemical as a Group 1 (Carcinogenic to Humans) when associated with the consumption of alcoholic beverages (IARC, 2012; REACH). However, it must be noted that this IARC Group 1 classification relates to a non-industrial use of the chemical.

H. Reproductive and Developmental Toxicity

Based on the available data, the chemical is not considered to cause reproductive and developmental toxicity. A NOAEL of greater than 400 mg/kg bw/day was reported for reproductive and developmental toxicity in rats (REACH).

In a reproductive and developmental toxicity screening test the chemical was administered orally to 22 rats at 400 mg/kg bw/day from day 6 through to day 15 of gestation. There were no maternal or developmental effects recorded at that dose level.

The chemical was also investigated in several studies for developmental effects following intraperitoneal injection of either a single dose of 0, 50, 75 or 100 mg/kg bw/day on gestation day 10, 11 or 12, or repeated doses of 0, 50, 75 or 100 mg/kg bw/day on gestation days 10 to 12 (CERI, 2007). Foetal resorptions, malformation (oedema, microcephaly, micrognathia, exencephaly and hydrocephaly), retarded development, and decreases in foetal body and placenta weight were observed in the groups given 50 mg/kg and above. However, exposure via the intraperitoneal route is not appropriate for the evaluation of a hazard or risk to humans from industrial use of the chemical. One CERI study examined the developmental effects of the chemical after oral exposure to rats. Pregnant rats were administered a dose of 200 mg/kg/day (3 % water solution) on gestation days 6 to 18. An anomaly of the ribs and vertebrae was observed in the foetuses. In addition, delayed ossification and hypoplasia of the cranial bones and sternum were observed. However, a reliable NOAEL could not be derived from this study due to insufficient data.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for acetaldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from available studies is 675 mg/kg-day based on a lack of effects in rats from a 28-day drinking water study (Til et al., 1988) (Kl = 2). Effects observed at this dose attributed to acetaldehyde (hyperkeratosis of the forestomach) likely resulted from direct contact irritation rather than the substance, and other effects (increased relative kidney weights in males, decreased urinary production, and variations in serum biochemistry) were attributable to reduced water intake. The NOAEL of 675 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 675/(10 x 10 x 1 x 10 x 1) = 675/1000 = 0.7 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)

Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.7 x 70 x 0.1)/2 = 3 mg/L

B. Cancer

A cancer reference value was not developed for acetaldehyde because it is not considered carcinogenic via the oral exposure route. The chemical is classified by the International Agency for Research on Cancer (IARC) as Group 2B (possibly carcinogenic to humans) based on sufficient evidence of carcinogenicity in experimental animals via inhalation (IARC, 1999). The chemical produced tumours of the respiratory tract in rats and hamsters following inhalation exposure at concentrations as low as 750 ppm, particularly adenocarcinomas and squamous cell carcinomas of the nasal mucosa in rats and laryngeal carcinomas in hamsters.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Acetaldehyde is extremely flammable.

Acetaldehyde does not exhibit the following physico-chemical properties:
· Explosivity
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies conducted on acetaldehyde.

Table 2: Acute Aquatic Toxicity Studies on Acetaldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hr LC_{50}	30.8	2	ECHA
Daphnia magna	48-hr EC_{50}	48.3	2	ECHA
Nitzscheria linearis	120-d EC_{50}	>237 and <249	2	ECHA

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for acetaldehyde follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (30.8 mg/L), invertebrates (48.3 mg/L), and algae (>237 and <249 mg/L). On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported E(L)C_{50} value of 30.8 mg/L for fish. The $PNEC_{water}$ is 0.3 mg/L.

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.012 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.06/1500) \times 1000 \times 0.3$
$= 0.012$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 3.219 \times 0.02$
$= 0.06$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for acetaldehyde based on the log K_{ow} is 3.219 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Acetaldehyde is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on an estimated log K_{ow} of -0.34 (EPA, 2019), acetaldehyde does not meet the screening criteria for bioaccumulation.

There are no chronic toxicity studies on acetaldehyde. The acute E(L)C_{50} values are >1 mg/L for fish, invertebrates, and algae. Thus, acetaldehyde does not meet the screening criteria for toxicity.

Thus, acetaldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Damage/Irritation: Category 2A
Flammable Liquids: Category 1
Specific target organ toxicity - Single Exposure Category 3 (respiratory tract irritation)

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Remove contact lenses if present and easy to do. Continue rinsing. Seek immediate medical assistance.

Skin Contact
Wash affected area thoroughly with copious amounts of running water. Remove contaminated clothing and wash before reuse. Seek medical attention.

Inhalation
If inhaled, remove from contaminated area to fresh air immediately. Apply artificial respiration if not breathing. If breathing is difficult, give oxygen. Consult a physician.

Ingestion
Rinse mouth thoroughly with water immediately, repeat until all traces of product have been removed. DO NOT INDUCE VOMITING. Seek immediate medical advice

Notes to Physician
Treat symptomatically based on judgement of doctor and individual reactions of the patient. Persons with kidney disease, chronic respiratory disease, liver disease, or skin disease may be at increased risk from exposure to this substance.

Medical Conditions Aggravated by Exposure
Persons with kidney disease, chronic respiratory disease, liver disease, or skin disease may be at increased risk from exposure to this substance.

Emergency Personnel Protection
Avoid skin and eye contact with – and inhalation of – this chemical. Acetaldehyde must be kept away from heat/sparks/open flames/hot surfaces.

B. Fire Fighting Information

Extinguishing Media
Caution: Use of water spray when fighting fire may be inefficient.
Small fire: Use alcohol resistant foam, dry chemical, CO2 or water spray.
Large fire: Use alcohol resistant foam, fog or water spray - Do not use water jets.

If safe to do so, move undamaged containers from fire area. Cool containers with flooding quantities of water until well after fire is out. Avoid getting water inside containers.

Specific Exposure Hazards
Hazards from combustion products may include: methane, other toxic, irritating chemicals, carbon monoxide, carbon dioxide, and peroxides (in air).

HIGHLY FLAMMABLE
Low flashpoint - Will be easily ignited by heat, sparks or flame. Vapours will form explosive mixtures with air. Vapours may travel to source of ignition and flash back. Vapour is heavier than air and will collect in low or confined areas (drains, basements, tanks). Liquids is lighter than water. Containers may explode when heated. Fire will produce irritating, poisonous and/or corrosive gases. Vapours from runoff may create explosion hazard

Special Protective Equipment for Firefighters
Wear SCBA and fully-encapsulating, gas-tight suit when handling these substances. Structural firefighter's uniform is NOT effective for these materials.

C. Accidental Release Measures

Personal Precautions
Evacuate unprotected persons. Avoid inhalation and avoid contact with skin, eyes and clothing.

Environmental Precautions
Prevent entry into waterways, drains or confined areas.

Steps to be Taken if Material is Released or Spilled
ELIMINATE all ignition sources (no smoking, flares, sparks or flame) within at least 50m - All equipment used when handling the product must be earthed. Do not touch or walk through spilled material. Stop leak if safe to do so. Vapour-suppressing foam may be used to control vapours - Water spray may be used to knock down or divert vapour clouds.

Absorb with earth, sand or other non-combustible material. Use clean, non-sparking tools to collect absorbed material and place it into loosely-covered metal or plastic containers for later disposal.

D. Storage And Handling

General Handling

Avoid ingestion and inhalation of dust, vapour, fumes, spray mist, or gas. Avoid contact with eyes, skin, or clothing. Avoid prolonged or repeated exposure. Handle under an inert atmosphere. Store protected from air. This product may be under pressure; cool before opening.

Use only with adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Wear suitable protective clothing. Ground and bond containers when transferring material. Take precautionary measures against static discharges. Empty containers retain product residue, (liquid and/or vapour), and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose empty containers to heat, sparks or open flames.

Other Handling Precautions

If peroxide formation is suspected, do not open or move container. Open carefully. Avoid all contamination. Always open containers slowly to allow any excess pressure to vent. Keep container tightly closed when not in use.

Corrosivity to Metals: Dry, pure acetaldehyde is not corrosive to metals. In air, acetaldehyde can be oxidized to acetic acid, which is corrosive to some metals. Acetaldehyde vapour leaking into a building equipped only with flameproof electrical equipment ignited, possibly on contact with rusted steel, corroded aluminium or hot steam lines.
Corrosivity to Non-Metals: Acetaldehyde attacks some plastics.

Storage

Keep away from heat, and all sources of ignition (sparks and flame). Ground all equipment containing material.

Store in a segregated, approved location, in a cool, dry, dark, well-ventilated area away from incompatible materials. This product should be stored away from foodstuffs, strong oxidizing agents, strong acids, reducing agents, combustible materials, organic materials, metals, and alkalis.
Protect against physical damage, air and sunlight (UV light). Air sensitive. Do not expose to air. May develop pressure. Store in explosion-proof refrigerator. Keep from freezing. After opening, purge container with nitrogen before reclosing. Periodically test for peroxide formation on long-term storage. Addition of water or appropriate reducing materials will lessen peroxide formation. Store only if stabilized.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

A time weighted average (TWA) has been established for acetaldehyde (Safe Work Australia) of 36 mg/m^3, (20 ppm). The corresponding STEL level is 91 mg/m^3 (50 ppm).

Engineering Controls
Maintain the concentration values below the TWA. This may be achieved by process modification, use of local exhaust ventilation, capturing substances at the source, or other methods.

Personal Protection Equipment
Respiratory Protection:
Where ventilation is not adequate, respiratory protection may be required. When mists or vapours exceed the exposure standards then the use of the following is recommended: approved respirator with organic vapour and dust/mist filters. Filter capacity and respirator type depends on exposure levels.

Hand Protection:
Protective gloves. Recommendation:
Excellent: Butyl rubber gloves Silver Shield gloves
Fair: NR latex and neoprene.
Poor: Vinyl gloves. PVC or nitrile rubber gloves.

Skin Protection:
Long sleeved clothing

Eye protection:
The use of a face shield, chemical goggles or safety glasses with side shield protection as appropriate.

Other Precautions:
No data available.

F. Transport Information

UN Number 1089
Transport hazard class 3

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

RIFM, 1976. Report on Human Maximization Studies. Research Institute for Fragrance Materials (RIFM). RIFM Report No. 1796, August 27, 1976.

Silverman L, Schultes HF and First MW (1946). Further studies on sensory response to certain industrial solvent vapors. J Ind Hyg Toxicol 28: 262-266.U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ACETIC ACID

This dossier on acetic acid presents the most critical studies pertinent to the risk assessment of acetic acid in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Acetic acid

CAS RN: 64-19-7

Molecular formula: $C_2H_4O_2$

Molecular weight: 60.1

Synonyms: Acetic acid, ethanoic acid, ethylic acid, methane carboxylic acid, vinegar acid, acetic acid (glacial)

SMILES: CC(=O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Acetic Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless liquid with a pungent odor.	2	ECHA
Melting Point	16.64°C	2	ECHA
Boiling Point	117.9°C	2	ECHA
Density	1.04 g/cm^3	2	ECHA
Vapor Pressure	20.79 hPa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-0.17	2	ECHA

Property	Value	Klimisch score	Reference
Water Solubility	602.9 g/L	2	ECHA
Flash Point	39°C @ 101.3 kPa	2	ECHA
Auto flammability	463°C	2	ECHA
Viscosity	1.056 mPa s @ 25°C	2	ECHA
Dissociation constant	4.756 @ 25°C	2	ECHA

Acetic acid readily dissociates in aqueous media to the acetate ($H_3C2O_2^-$) and hydrogen (H^+) ions.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The acetate ion of acetic acid is readily biodegradable, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Biodegradation

Acetic acid was readily biodegradable a non-acclimated freshwater study. Degradation was 96% after 20 days (Price et al., 1974; ECHA) [Kl. score = 2]. Acetic acid is also readily biodegradable under anaerobic conditions (Kameya et al., 1995) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for acetic acid. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} values from log K_{ow} and the molecular connectivity index (MCI) are 1.153 and 1.0 L/kg , respectively.

D. Bioaccumulation

There are no bioaccumulation studies on acetic acid. Bioaccumulation of acetic acid is not expected to occur because acetic acid dissociates completely in aqueous solution to acetate and its hydrogen ion. Both ions are ubiquitous in the environment. Acetate is naturally found in eukaryotic and prokaryotic cells and is involved in multiple biochemical pathways.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Acetic acid is a corrosive liquid. Depending on the concentration, aqueous solutions of acetic acid are either corrosive, irritating, or non-irritating to the skin, eyes, and gastrointestinal tract. Vapours from aqueous solutions of acetic acid can cause respiratory irritation. There are no adequate repeated dose toxicity studies on acetic acid. Acetic acid is not genotoxic. Positive findings have been reported in some *in vitro* genotoxicity studies, and are considered to be the result of the pH change in the test system. Animals studies have shown no developmental toxicity from ingestion of acetic acid.

B. Acute Toxicity

The oral LD_{50} of the sodium salt of acetic acid in rats is 3,310 mg/kg (Woodard et al., 1941; ECHA) [Kl. score =2]. The oral LD_{50} of the acetic acid in unfasted rats is 3,530 mg/kg (ECHA) [Kl. score =4]. The oral LD_{50} of the sodium salt of acetic acid in mice is 4,960 mg/kg (Smyth et al., 1951; ECHA) [Kl. score =2].

The 4-hour inhalation LC_{50} in rats for acetic acid vapor is 11.4 mg/L. There were clinical signs that were indicative of corrosion (ECHA) [Kl. score = 2].

C. Irritation

Application of a 3.3% or a 10% aqueous solution of acetic acid to the skin of rabbits for 4 hours was slightly irritating. The Primary Dermal Irritation Index scores were 0.5 and 1.1, respectively (Nixon et al., 1990; ECHA) [Kl. score = 2]. Application of a 10% solution of acetic acid to the skin of rabbits for 4 hours under semi-occlusive conditions was slightly irritating (ECHA) [Kl. score = 2].

Instillation of 0.1 mL of a 10% solution of acetic acid to the eyes of rabbits was considered irritating. The mean of the 24, 48, and 72 hours scores were: 2.67 for erythema; 1.67 for chemosis; 1.72 for corneal opacity; and a mean of 87% corneal swelling (Jacobs and Martens, 1989; ECHA) [Kl. score = 2]

D. Sensitization

No studies are available.

E. Repeated Dose Toxicity

Oral
No adequate studies for human health risk assessment are available.

Inhalation
No studies are available.

Dermal
No adequate studies for human health risk assessment are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on acetic acid are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Acetic Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	NC	-	2	Ishidate et al. (1984); ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Zeiger et al. (1992); ECHA
Chromosomal aberrations (CHO cells)	-**	-**	2	Morita et al. (1990); ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-***	-***	2	Seifried et al. (2006); ECHA

*+, positive; -, negative; NC, not conducted.
**A dose-dependent increase in chromosomal aberrations was observed with 10 mM acetic acid (-S9) and 8 mM acetic acid (+S9). These concentrations were close to the cytotoxic limit at which the cells could no longer be evaluated. These effects were abolished by neutralizing the test medium or increasing the buffer capacity. These results suggest that the positive findings are due to the acidic pH of the incubation medium rather than a consequence of an intrinsic clastogenic potential of acetic acid.
***Acetic anhydride (hydrolyzes to acetic acid in aqueous media).

In vivo Studies

No studies are available on acetic acid.

A bone marrow micronucleus study has been conducted on acetic anhydride (which hydrolyses to acetic acid). Male and female SD rats were exposed by inhalation to 0, 1, 5, or 20 ppm acetic anhydride, 6 hours/day, 5 days/week for 13 weeks. The incidence of micronucleated immature erythrocytes was not increased at any exposure concentration (ECHA) [Kl. score = 1]

G. Carcinogenicity

No oral or inhalation studies are available.

No deaths nor skin tumors were seen when acetic acid was applied dermally once a week to CD-1 mice for 32 weeks (Slaga et al., 1975; ECHA) [Kl. score = 4].

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0 or various concentrations up to 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 15. There were no maternal or developmental toxicity effects noted at any dose level. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day (ECHA). [Kl. score = 2]

Pregnant female CD-1 mice were dosed by oral gavage with 0, 16, 74.3, 345, or 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 15. There were no treatment-related effects on maternal or fetal survival, or on soft or skeletal tissues. There was no effect on the fetal development in the presence of slight maternal toxicity (reduced body weight gain) at 345 mg/kg. At 1,600 mg/kg, there was an increase in the number of litters containing a dead fetus and some reductions in ossification. The NOAELs for maternal and developmental toxicity are 74.3 and 345 mg/kg-day, respectively (ECHA). [Kl. score = 2]

Pregnant female Dutch-belted rabbits were dosed by oral gavage with 0, 16, 74.3, 345, or 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 18. There were no treatment-related effects on maternal or fetal survival, or on soft or skeletal tissues. There was a reduction in the pregnancy rate in the high-dose group; and a dose-dependent decrease in maternal body weights at $\geq$74.3 mg/kg. Some deaths or abortions occurred in all treated groups and some litter losses were reported at $\geq$345 mg/kg. Maternal effects were much more noticeable than the effects on fetal

development. These findings have been considered a consequence of the bactericidal properties of orally administered acetic acid within the gastrointestinal tract of female rabbits, and not a direct effect on embryonic implantation and development of acetic acid (EU, 2008). It is likely that this accounts for the apparent increased sensitivity of this species to oral administration of acetic acid. The NOAEL for developmental toxicity is 1,600 mg/kg-day; a NOAEL for maternal toxicity was not identified (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for acetic acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

There are no repeated dose toxicity studies that were considered adequate for human health risk assessment.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has maintained a group ADI of "not limited" for acetic acid and its potassium and sodium salts (JECFA).

While concentration of acetic acid will affect pH, and extreme pH values (<4 and >11) may adversely affect health, there are insufficient data to set a health guideline value (ADWG, 2011)

B. Cancer

There are no carcinogenicity studies by the oral or inhalation route. A dermal carcinogenicity study in mice showed no carcinogenic activity when acetic acid was applied to the skin for 32 weeks. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Acetic acid is a flammable liquid.

Acetic acid does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acetic acid is of moderate acute toxicity concern to aquatic organisms, in part because of the effect of pH changes from the dissociated hydrogen ion. The acetate ion is of low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 presents the results of acute aquatic toxicity studies on acetic acid and potassium acetate.

Table 3: Acute Aquatic Toxicity Studies on Acetic acid and Potassium Acetate

Test Substance	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Potassium acetate	*Oncorhynchus mykiss*	96-h LC_{50}	>300.82*	2	ECHA
Potassium acetate	*Danio rerio*	96-h LC_{50}	>300.82*	2	ECHA
Acetic acid	*Oncorhynchus mykiss*	96-h LC_{50}	64.8 (measured)	4	ECHA
Acetic acid	*Oncorhynchus mykiss*	96-h LC_{50}	31.3 – 67.6	4	ECHA
Potassium acetate	*Daphnia magna*	48-h EC_{50}	>300.82*	2	ECHA
Acetic acid	*Daphnia magna*	48-h EC_{50}	79.5 (measured)	4	ECHA
Acetic acid	*Daphnia magna*	48-h EC_{50}	18.9	4	ECHA

Test Substance	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
			(measured)		
Acetic acid	*Desmodesmus subspicatus*	72-h EC_{50}	486.5	4	ECHA

*As the acetate ion.

Chronic Studies

In a 21-day fish (*Oncorhynchus mykiss*) chronic study, the measured NOEC values for 60% and 100% acetic acid were 57.2 and 34.3 mg/L, respectively (ECHA). [Kl. score = 4]

In a 21-day *Daphnia* reproduction study, the measured NOEC for 60% and 100% acetic acid were 80 and 31.4 mg/L, respectively (ECHA). [Kl. score = 4]

In a 21-day *Daphnia* reproduction study, the measured NOEC for 100% acetic acid was 22.7 mg/L (ECHA). [Kl. score = 4]

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

Despite the low Klimisch scores for aquatic toxicity testing (K=4), the PNEC calculations for acetic acid follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. For the acute toxicity studies, data are available on both acetic acid and potassium acetate; both substances dissociate completely in aqueous media to the acetate anion and the corresponding cations (H^+ and K^+). The toxicity of these substances is expected to be driven by the acetate ion, with the cations having a minor role. The toxicity data on potassium acetate are preferred because of the absence of a potential pH change from the dissociated H^+ ion of acetic acid. For the chronic toxicity studies, only acetic acid has been tested for two trophic levels: fish and invertebrates. These studies will not be used to derive the PNEC value; however, an assessment factor of 100 will be applied to the lowest acute $E(L)C_{50}$ values.

From the potassium acetate studies, acute $E(L)C_{50}$ values (adjusted for acetic acid) are available for fish (300.82 mg/L) and *Daphnia* (300.82 mg/L). By applying an assessment factor of 100 to the $E(L)C_{50}$ value of 300.82 mg/L from either fish or *Daphnia*, the $PNEC_{aquatic}$ for acetic acid is 3.0 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 1.9 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.82/1280) \times 1000 \times 3.0$
$= 1.9$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.82$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 1.0 \times 0.04$
$= 0.04$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for acetic acid calculated from EPISUITE™ using the MCI is 1.0 L/kg .
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.04 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 3.0
= 0.04

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
= 1.0 x 0.02
= 0.02

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for acetic acid calculated from EPISUITE™ using the MCI is 1.0 L/kg .
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Acetic acid is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Bioaccumulation of acetic acid is not expected to occur because acetic acid dissociates completely in aqueous media to acetate and its hydrogen ion. Both ions are ubiquitous in the environment. Acetate is naturally found in eukaryotic and prokaryotic cells and is involved in multiple biochemical pathways. The log K_{ow} for acetic acid is -0.17. Thus, acetic acid does not meet the screening criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on acetic acid are >0.1 mg/L. The $E(L)C_{50}$ values for potassium acetate are > 1 mg/L. Thus, acetic acid does not meet the criteria for toxicity.

Thus, acetic acid is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 3
Skin Corrosion Category 1A

EU:
≥90%: Skin Corrosion 1A
≥25% to <90%: Skin Corrosion 1B
≥10% to <25%: Skin irritant Category 2; Eye irritant Category 2

In addition to the hazard statements corresponding the GHS classifications (if Skin Corrosion 1A or 1B is included), the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention immediately.

Inhalation
Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion
Rinse mouth and lips with plenty of water if person is conscious. Do not induce vomiting. Do not use mouth-to-mouth method if victim had ingested the substance. Obtain medical attention immediately if ingested.

Notes to Physician
Treat as a corrosive due to pH of the material. All treatments should be based on observed signs and symptoms of distress in the patient.

A. Fire Fighting Information

Extinguishing Media
Use water spray or fog, foam, dry chemical or carbon dioxide. Do not use straight streams of water.

Specific Exposure Hazards
Flammable liquid and vapor. Vapors are flammable and heavier than air. Vapors may travel across the ground and reach remote ignition sources causing a flashback fire danger. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters
Structural firefighter's protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible. Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Wear positive pressure self-contained breathing apparatus (SCBA). Move containers from fire area if you can do it without risk.

B. Accidental Release Measures

Personal Precautions
Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapors, or spray Avoid contact with skin, eye, and clothing. Eliminate all sources of ignition.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Eliminate all sources of ignition. All equipment used when handling the material must be grounded. A vapor suppressing foam may be used to reduce vapors. Use clean non-sparking tools to collect absorbed material. Pick up with suitable absorbent material

and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

C. Storage And Handling

General Handling

Prevent exposure to ignition sources (i.e., use non-sparking tools and explosion-proof equipment). Avoid contact with eyes, skin, and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation. Use proper bonding and/or ground procedures. However, bonding and grounds may not eliminate the hazard from static accumulation. Peroxides may form upon prolonged storage. Exposure to light, heat or air significantly increases peroxide formation. If evaporated to a residue, the mixture of peroxides residue and material vapor may explode when exposed to heat or shock.

Storage

Keep container tightly closed. Store in a cool, well-ventilated area away from heat and light. Storage containers should be grounded and bonded. Fixed storage containers, transfer containers and associated equipment should be grounded and bonded to prevent accumulation of static charge.

D. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for acetic acid in Australia is 10 ppm (25 mg/m^3) as a 8-hr TWA and 15 ppm (37 mg/m^3) as a 15-min STEL.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection:

If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus.

Hand Protection:
Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection:
Use protective clothing chemically resistant to the this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection*:*
Use chemical goggles.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

E. Transport Information

For glacial acetic acid or >80% acetic acid solutions:

UN 2789 (ACETIC ACID, GLACIAL or ACETIC ACID SOLUTION)
Class: 8
Packing Group: II

For ≥50% to 80% acetic acid solutions:

UN 2790 (ACETIC ACID SOLUTION)
Class: 8
Packing Group: II

For >10% to <50% acetic acid solutions:

UN 2790 (ACETIC ACID SOLUTION)
Class: 8
Packing Group: III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Ishidate, M., Jr., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., and Matsuoka, A. (1984). Primary mutagenicity screening of food additives currently used in Japan. Fd. Chem. Toxicol. 22: 623-636.

Jacobs, G.A., and Martens, M.A. (1989). An objective method for the evaluation of eye irritation in vivo. Fd. Chem. Toxicol. 27: 255-258.

JECFA: http://apps.who.int/ipsc/database/evaluations/chemical.aspx?chemID=4785.

Kameya, T., Murayama, T., Urano, K., and Kitano, M. (1995). Biodegradation ranks of priority organic compounds under anaerobic conditions. Sci. Total Environ. 170: 43-51.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Morita, T., Takeda, K., and Okumura, K. (1990). Evaluation of clastogenicity of formic acid, acetic acid and lactic acid. Mutat. Res. 240: 195-202.

Nixon, G.A., Bannon, E.A., Gaynor, T.W., Johnston, D.H., and Griffith, J.F. (1990). Evaluation of modified methods for determining skin irritation. Regul. Toxicol. Pharmacol. 12: 127-136.

Price, K.S., Waggy, G.T., and Conway, R.A. (1974). Brine shrimp bioassay and seawater BOD of petrochemicals. J. Water Pollut Control Fed. 46: 63- 77.

Seifried, H.E., Seifried, R.M., Clarke, J.J., Junghans, T.B., and San, R.H.C. (2006) A compilation of two decades of mutagenicity test results with the Ames Salmonella typhimurium and L5178Y mouse lymphoma cell mutation assays. Chem. Res. Toxicol. 19: 627-644.

Slaga, T., Bowden, G., and Boutwell, R. (1975). Acetic acid, a potent stimulator of mouse epidermal macromolecular synthesis and hyperplasia but with weak tumor-promoting ability. Natl. Cancer Inst. 55: 983-987.

Smyth, H.F., Carpenter, C.P., and Weil, C. (1951). Range-finding toxicity data: list IV. Arch. Ind. Hyg. 4: 119-122.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Woodard, G., Lange, S.W., Nelson, K.W., and Calvery, H.O. (1941). The acute oral toxicity of acetic, chloroacetic, dichloroacetic, and trichloroacetic acids. J. Ind. Hyg. Toxicol. 23: 78-82.

Zeiger, E., Anderson, B., Haworth, S., Lawlor, R., and Mortelmans, K. (1992). Salmonella mutagenicity tests: V. Results form the teting of 311 chemicals. Environ. Mol. Mutagen. 19(Suppl. 21): 2-141.

ACRYLONITRILE

This dossier presents the most critical studies pertinent to the risk assessment of acrylonitrile in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Propenenitrile

CAS RN: 107-13-1

Molecular formula: C3H3N

Molecular weight: 53.064

Synonyms: Acrylonitrile monomer, Cyanoethene, Cyanoethylene, Propenenitrile, Vinyl cyanide, Vinylcyanide

SMILES: C1=CC=C(C=C1)C=CC#N

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Acrylonitrile

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, colorless liquid with a faintly pungent odor.	2	ECHA
Melting point	-83.5°C	2	ECHA
Boiling point	77.3°C	2	ECHA
Density	0.8004 g/cm^3 @ 25°C 0.81 g/cm^3 @ 20°C	2	ECHA

Property	Value	Klimisch score	Reference
Vapor pressure	11.5 kPa @ 20°C 133.3 hPa @ 23.6°C	2	ECHA
Partition coefficient (log K_{ow})	1.04 @ 21°C	2	ECHA
Water solubility	73 g/L @ 20°C	2	ECHA
Flash point	0°C	2	ECHA
Auto flammability	481°C	2	ECHA
Viscosity	0.34 mPa s @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Acrylonitrile is inherently biodegradable. Several studies indicate that acrylonitrile does not meet the criteria for ready biodegradability. However, other studies suggestive of environmental non-persistence show significant decreases in concentration in environmental media. Acrylonitrile does undergo biodegradation in a variety of circumstances; it does not meet criteria for bioaccumulation.

B. Biodegradation

Acrylonitrile is inherently biodegradable.

In an inherent biodegradability:modified MITI II (OECD 302C) test, degradation was 61% after 14 days (determined by BOD (NO_2)); 96% after 14 days (determined by BOD (NH_3)); 100% after 14 days (determined by TOC removal); and 100% after 28 days (determined by GC) (ECHA) [Kl. score = 1].

In an inherent biodegradability:modified MITI I (OECD 301C) test, degradation was 15% after 28 days (determined by BOD (NO_2)); 23% after 28 days (determined by BOD (NH_3)); 38% after 28 days (determined by TOC removal); and 44% after 28 days (determined by GC) (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for acrylonitrile. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} method is 28.55 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 8.51/kg.

D. Bioaccumulation

There are no bioaccumulation studies on acrylonitrile. Acrylonitrile is not expected to bioaccumulate based on a log K_{ow} of 0.017 (ECHA) nor does study need to be conducted because the substance has a low potential for bioaccumulation based on log Kow <=3 (ECHA 2019)

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Acrylonitrile is listed in Annex VI of the CLP Regulation (1272/2008/EC) with classification in Acute Toxicity Category 3, H301: Toxic if swallowed, H311: Toxic in contact with skin and H331: Toxic if inhaled. The available data are consistent with this harmonised classification and no change is proposed.

The acute toxicity data for acrylonitrile were reviewed in detail in the EU Risk Assessment Report (2004). The following summary is based largely on the EU RAR, supplemented by literature reviews conducted in 2014 and, more recently, in March 2017.

B. Acute Toxicity

Oral

The EU RAR (2004) reviews the available data on the acute oral toxicity of acrylonitrile. Oral LD50 values for various species are reported to be in the range 25 -186 mg/kg bw with a species sensitivity of mouse>guinea pig>rabbit and rat. Following oral dosing, the mouse appears to be the most sensitive species, with oral LD50 values ranging from 28-48 mg/kg bw. The reported range in the guinea pig is 50-85 mg/kg bw, an oral LD50 of 93 mg/kg bw is reported in the rabbit, while in the rat the range of reported LD50 values is 72 -186 mg/kg bw (EU RAR, 2004).

Vernon et al., in a study carried out in 1969 but reported in the Journal of the American College of Toxicology in 1990, orally dosed four groups of 5 young adult male CF Nelson rats with 50, 100, 200 and 400 mg/kg bw acrylonitrile and observed them for 14 days.

All deaths occurred during the first 24 hours with no significant clinical signs being observed; the acute oral LD50 was calculated to be 81 (62 -107) mg/kg bw.

Rao et al. (2013) report an acute 24-hour LD50 of 95.1 mg/kg bw in female Wistar rats. The acute oral LD50 of acrylonitrile is lower in mice than in rats, as would be expected based on the comparative metabolism. The oral LD50 in mice was reported by Tullar (1947) to lie between 25-48 mg/kg bw, as summarised in WHO (1983). Tanii & Hashimoto (1984) reported similar values of 27 and 38 mg/kg bw. These values, however, appear artificially low relative to other studies. For instance, Ghanayem et al. (2002) dosed mice with 20 mg/kg bw/d on five days per week for 2 years without any observable cyanosis. Leonard (1981) also dosed mice with 30 mg/kg bw and found no lethality. Tanii (1989) administered mice 60 mg/kg bw and observed 80% mortality, but subsequently administered 79 mg/kg bw without lethality. Data indicate that mice excrete a higher percentage of administered acrylonitrile as thiocyanate (and hence appear to metabolise more acrylonitrile to cyanide) than rats or humans (EU RAR, 2004). Reported oral LD50 values for acrylonitrile in various species lie in the range 25 -186 mg/kg bw (GDCh/BUA, 1995). No human data are identified.

Dermal

Dermal LD50 values for various species are in the range 148 -693 mg/kg bw, with the rat being the most sensitive species (BUA, 1995). In a study by Vernon et al. (1969) a single dose of 200 mg/kg bw was applied to the intact skin of 15 young adult male rabbits and occluded for an exposure period of 24 hours. This study resulted in death of all animals within the first 24 hours, with no clinical signs being noted. The acute dermal LD50 of acrylonitrile in this study was therefore <200 mg/kg bw. Roudabush et al. (1965) reported an LD50 for the rabbit of 226 mg/kg bw. In a more recent rat study (SNF, 2005), acrylonitrile administered topically with occlusion at a dose level of 200 mg/kg bw for 4 hours resulted in 10% mortality (1 of 10 rats). While some human data also indicate a potential for systemic toxicity following dermal exposure to acrylonitrile, conclusive data suitable for determination of a human dermal LD50 or other such metric are not available.

Inhalation

The LC50 values reported for a range of species following a 4-hour inhalation exposure lie in the concentration range of 0.3 -1.21 mg/L. Dudley & Neal (1942) investigated the susceptibility of rats, guinea pigs, rabbits, cats, dogs and monkeys to a single 4-hour exposure to varying concentrations of acrylonitrile. The results indicated that rabbits were moderately susceptible; exposure to 260 ppm (0.56 mg/L) for 4 hours caused 100% mortality in 4 -5 hours, while a level of 135 ppm produced marked but transitory effects. Rats and cats were of about equal susceptibility, 100% mortality being observed in rats within 2–6 hours of exposure to 635 ppm (1.38 mg/L) and in cats within 1.5 hours of exposure to 600 ppm (1.30 mg/L). Exposure of two monkeys to 90 ppm (0.196 mg/L) produced only slight transitory effects. Delayed mortality (25%) was observed in guinea pigs exposed to a level of 575 ppm (1.25 mg/L) as a result of lung oedema 3 -5 days

following exposure. In general guinea pigs appeared to be less sensitive than rats following inhalation exposure, but the lethality in both species after administration by other routes is comparable. Dudley & Neal (1942) report that the dog was the most sensitive species. Exposure to 110 ppm (0.24 mg/L) acrylonitrile was fatal in 2 out of 3 dogs exposed, while a 4-hour exposure to a level of 100 ppm resulted in convulsions followed by coma in 2 out of 3 dogs. One of these dogs recovered completely within 48 hours while the other showed partial paralysis of the hind legs for 3 days. The third dog exposed to 100 ppm acrylonitrile showed severe salivation during the test but recovered fully within 24 hours. At an exposure level of 29 ppm (0.063 mg/L) for 4 hours, signs of toxicity in dogs were confined to slight salivation.

With regard to the acute lethality of aceylonitrile in animals, dogs appeared to be the most sensitive species following exposure via inhalation but the dataset for dogs is limited. At least some of the species variability in the toxic response to acrylonitrile may be a function of the cyanide metabolite and activity levels of rhodanese. It is reported that dogs have relatively low concentrations of rhodanese and rats have relatively high concentrations; overall species variability was about 3-fold. Data from studies of rats provide the most extensive evaluation of exposure durations and the best definition of dose response. A total of seven rat studies were identified that contain information useful for calculating the 4 -hour or 1 -hour LC50 of acrylonitrile.

C. Irritation

A number of skin irritation and eye irritation studies are available. Studies are of variable design but indicate that acrylonitrile is a skin irritant (but not corrosive) and a severe eye irritant. The animal data are also consistent with experiences of accidentally exposed workers. Findings from animal studies and human experience also indicate that the substance is a respiratory irritant.

In a guideline-comparable study (Vernon et al., 1990), 0.5 mL acrylonitrile was applied for 24 hours under occlusive conditions to the shorn (intact and abraded) dorsal skin of six New Zealand White rabbits. Dermal reactions were assessed at 24 and 72 hours following application and mean scores (24 and 72 hour) scores (on a scale of 0 to 4) for both erythema and oedema are reported. The mean score both erythema and oedema was 3.6, with slightly higher scores reported for abraded skin. This study that acrylonitrile is a skin irritant and should be classified as such. The EU RAR also reviews the available animal data on the skin irritation of acrylonitrile. The dataset consists of two studies, the most reliable of which is that of Vernon et al (1990). Both studies are consistent in indicating that acrylonitrile is a skin irritant. The animal data are consistent with experience of skin irritation in workers following accidental exposure. No further testing is proposed.

In a guideline-comparable study (DuPont, 1975), 0.1 mL acrylonitrile was instilled into in the conjunctival sac of the right eye of two rabbits. After 20 seconds the treated eye of

one of the rabbits was washed with tap water for 1 minute, the other rabbit remained unwashed. Corneal opacity/conjunctive irritation occurred up to 3 days in the washed eye and up to 21 days in the unwashed treated eye. Acrylonitrile was therefore found to be an eye irritant under the conditions of this study; the lack of complete reversibility of corneal effects within the 21-day study period supports the harmonised classification of the substance for serious eye damage (Cat 1). Several additional rabbit studies are reported in the EU RAR document; the individual study designs and quality vary, however the results are consistent in demonstrating that acrylonitrile is an eye irritant. The EU RAR concludes that classification of acrylonitrile for serious eye damage is appropriate. This classification is also consistent with human experience.

No specific animal studies of respiratory irritancy such as the Alarie test have been carried out. The EU RAR states that both long-term and short-term toxicity studies in a range of species indicate that acrylonitrile has irritant effects on the upper respiratory tract. Occupational exposure has also been reported to result in respiratory irritation.

D. Sensitization

Acrylonitrile is listed on Annex VI of the CLP Regulation with classification for skin sensitisation (H317: may cause an allergic skin reaction'. In addition, there are also reports of sensitisation in exposed workers.

A guideline-compliant maximisation assay using female SPF Dunkin-Hartley guinea pigs is also reported (Koopmans & Daamen, 1989). In this study, sensitisation was induced by intradermal injection of 2.5% acrylonitrile and an epidermal application of 2% acrylonitrile. Animals challenged with acrylonitrile concentrations of 0.5% and 1.0% acrylonitrile showed a 95% positive sensitisation rate. Exposure to 0.2% on challenge caused an 80% sensitisation rate while control animals exhibited a 5% sensitization rate.

No animal data are available for assessing respiratory sensitisation; there is no recognised validated test guideline for the investigation of this endpoint. There are no reports, from exposed workers of occupational asthma, which indicates that acrylonitrile does not have the potential to cause respiratory sensitisation.

E. Repeated Dose Toxicity

Repeated exposure to acrylonitrile results in damage to the kidney, gastrointestinal tract, central nervous system and adrenal gland. The respiratory tract is also affected following repeated exposure by inhalation. Dogs appear to be the most sensitive species to exposure to acrylonitrile by inhalation, with mortalities being seen at exposure levels causing no deaths in other species, however no reliable long-term oral study has been carried out in the dog. In relation to target organ toxicity, the central nervous system appears to be a primary target organ, with neurofunctional changes being observed, although the evidence for frank neurotoxicity is limited. Nephrotoxicity is observed at

high dose levels. Gastrointestinal lesions seen following oral dosing may in part be due to a local irritant effect. The neurotoxicity of acrylonitrile can partly be explained by cyanide released during metabolism. Other effects may occur through the alkylation of molecules in the central nervous system by the reactive epoxide metabolite CEO. Additionally, acrylonitrile itself is capable of non-enzymatically cyanoethylating essential functional groups in the body. All of these factors may contribute to the overall toxicity of acrylonitrile.

For repeated dose toxicity by the oral route, the key study is the F344 rat drinking water study of Johannsen & Levinskas (1980), from which a NOAEL of 3 ppm (equivalent to average daily dose levels of 0.25 mg/kg bw/d in males and 0.36 mg/kg bw/d in females) was derived. Groups of F344 rats were exposed to acrylonitrile in the drinking water for approximately 2 years as part of a combined chronic toxicity/carcinogenicity study, at doses of 0, 1, 3, 10, 30 and 100 ppm. The study was terminated at 23 months in females because of low survival rates. The males were exposed for 26 months. A consistent decrease in survival, reduced bodyweight and reduced water intake, and small reductions in haematology parameters were observed in both sexes of the 100 ppm group. Mortality was significantly increased compared to controls in the 100 ppm group, while mortality in the males receiving 10 ppm and the females receiving 3 and 30 ppm was also significantly greater than controls. Organ to body weight ratios at various study intervals were consistently elevated in the high dose groups, and were thought to be related to the lower body weights seen in this group. Due to the lack of a dose response relationship in the female mortality data, the NOAEL was considered to be 3 ppm for both males and females; equivalent to average daily dose levels of 0.25 mg/kg bw/d in males and 0.36 mg/kg bw/d in females.

A number of additional repeated dose oral toxicity studies are summarised in the EU RAR. Refer to this document for further documentation.

Dermal

No data are available for the repeated dose toxicity of acrylonitrile by the dermal route. However studies are not required as comprehensive data are available for repeated dose toxicity by the oral and inhalation routes. Testing by the inhalation route is considered to be most relevant (with regard to the likely route of occupational exposure) for volatile substances. Based on kinetic considerations, the systemic dermal toxicity of acrylonitrile is not predicted to be fundamentally different to that seen following oral and/or inhalation exposure, therefore specific data for this route are not required (ECHA) . Due to the irritant and sensitising properties of the substance, it is likely that the effects of repeated dose dermal exposure will be dominated by local (site of contact) effects which will severely limit systemic exposure to the substance and consequently limit the relevance of the study. The use of engineering controls and PPE will also minimise dermal exposure to the substance under normal occupational conditions. Testing is therefore not scientifically justified and additionally cannot be supported on grounds of animal welfare.

Inhalation

For repeated dose inhalation toxicity, the key study is the 2 -generation rat study of Nemec et al. (2008), a two-generation reproductive toxicity study in Sprague-Dawley rats; the data presented here relate to the repeated dose inhalation toxicity to parental animals. Twenty-five rats/sex/group were exposed to vapour atmospheres of acrylonitrile via whole-body inhalation at concentrations of 0, 5, 15, 45 and 90 ppm, 6 hours daily, on 7 days a week for 10 weeks. Males were exposed for 10 weeks prior to mating and throughout mating until one day prior to termination. Females were exposed for 10 weeks prior to mating and throughout mating, gestation, and lactation until 1 day prior to termination. Exposure of the dams was suspended for 5 days following parturition (lactation days 0 -4) to avoid confounding nesting and nursing behaviour and neonatal survival. Exposure of the dams resumed on Day 5; rats were removed from the litters for 6 hours exposure at about the same time each day. There were no exposure-related mortalities. Bodyweight gain was significantly reduced at 45 and 90 ppm. Food consumption was also reduced at these dose levels, but the difference was only significant at 90 ppm. Clinical signs indicative of the irritant properties of acrylonitrile were observed in rats exposed to 90 ppm throughout the exposure period and within 1 hour of cessation of exposure; the irritant effects of the test material did not generally persist to the following day. Acrylonitrile-related microscopic alterations were limited to morphologically similar nasal lesions in the F0 males and females at 45 ppm, F1 males at 5, 15, and 45 ppm, and the F1 females at 15 and 45 ppm. Four levels of the nasal cavity were examined microscopically for the 5, 15, and 45 ppm groups. Lesions showed a clear exposure-response relationship in incidence and included respiratory/transitional epithelial hyperplasia, sub-acute inflammation, squamous metaplasia, and/or degeneration of the olfactory epithelium. The majority of the lesions were present in the most rostral section (level I) of the nasal tissues examined and are consistent with site-of-contact irritation resulting from exposure to irritant chemicals as reported in the literature by a number of authors. All of the nasal lesions noted in this study are common findings in the nasal epithelium of the rat following sub-chronic to chronic inhalation exposure with an irritating compound and represent the effects of local irritation, rather than a systemic effect. No other treatment-related histopathological findings were noted at any exposure level. Based on the incidence of local irritant effects in the nasal cavity at all exposure levels, a NOAEC cannot be determined for this study. A LOAEC of 5 ppm was determined.

The EU RAR summarises a number of additional studies investigating the repeated exposure inhalation toxicity of acrylonitrile. The studies were not of standard design or are considered to be of questionable quality, and therefore are not considered to be of critical relevance for this dossier.

F. Genotoxicity

The genotoxicity of acrylonitrile has been extensively investigated in a large number of standard and non-standard studies in vivo. A number of expert reviews are also available.

In vitro and ex vivo Studies

The mutagenicity of acrylonitrile has been investigated in a large number of bacterial mutation assays. The results of studies in Salmonella strains sensitive to frameshift mutation (TA97, TA98, TA1537, TA1538) are almost entirely negative, whereas mostly positive results are reported in Salmonella strains (TA100, TA1530, TA1535, TA1950) carrying the hisG46 allele and sensitive to GC to AT base pair substitution. It is notable that studies in TA102, which is considered to be sensitive to oxidative damage, have proved to be largely negative. Studies of bacterial mutation in E. coli strains have given mixed results, although more recent studies in strains WP2, WP2uvrA, and WP2(PKM101) have more consistently reported positive results in the presence of metabolic activation. WP2 tester strains include an AT base pair as the critical site. Fungal studies in *S. cerevisiae* and *Schizosaccharomyces pombe* have given mixed results for gene mutation endpoints but more consistently positive results for chromosomal level mutation, both with and without metabolic activation. A positive result has also been reported for aneuploidy/non-disjunction in *Aspergillus nidulans*.

In mammalian cell studies, a number of positive results are reported for acrylonitrile in L5178Y mouse lymphoma cells (Tk locus) both with and without metabolic activation; negative results are reported for this cell line at the Oua locus. L5178Y cells are particularly sensitive to mutations, in part because they have a mutation in the P53 tumour suppressor gene, but also because they may be especially sensitive to oxidative damage. The results of studies in other cell lines are variable, with both negative and positive results reported. There is no consistent association with metabolic activation; some studies report positive results with activation only, others both with and without activation. Molecular analyses indicate that point mutations (for CEO involving AT and GC pairs) may predominate over deletion mutations. In mammalian cells, the potential of acrylonitrile to induce clastogenicity has been investigated in human peripheral blood lymphocytes, CHO, CHL and metabolically competent rat liver RL4 cell lines. Many studies have reported positive results for the induction of structural aberrations, with most requiring metabolic activation. There is no evidence for the induction of numerical aberrations.

In vivo Studies

Investigation of mutagenicity and clastogenicity in appropriate animal models is of most relevance in terms of carcinogenic potential; the models used generally incorporate

relevant toxicokinetic, toxicodynamic and metabolic factors all of which could potentially influence the genetic toxicity potential of the test substance.

Exposure of rats by inhalation to acrylonitrile at concentrations of up to 500 ppm for 90 days did not result in observable effects on cells of the bone marrow (Johnson et al., 1978). No effects were observed in the bone marrow cells of mice administered acrylonitrile by gavage at dose levels of up to 21 mg/kg bw/d for up to 30 days, following intraperitoneal injection with dose levels of up to 20 mg/kg bw/d for up to 30 days; similarly no effects were seen in the bone marrow of rats administered acrylonitrile by gavage at a dose level of 40 mg/kg bw/d for 16 days (Rabello-Gay & Ahmed, 1980). Leonard et al., (1981) showed no induction of bone marrow micronuclei or chromosomal aberrations following the intraperitoneal injection of a single dose of acrylonitrile at a dose level of 20 or 30 mg/kg bw. No increase in the proportion of bone marrow cells was demonstrated in mice following inhalation exposure to dose levels of up to 140 mg/kg bw/d equivalent (Zhurkov et al., 1983) or following a single intraperitoneal injection of up to 60 mg/kg bw (Sharief et al., 1986). Similar negative effects were seen in mice administered acrylonitrile by single or repeated intraperitoneal injection (10 mg/kg bw) or by single (5, 10 mg/kg bw) or repeated (20 mg/kg bw) gavage dosing (Nesterova et al., 1999). The high quality NTP study (NTP, 2001) also showed no evidence of increased micronuclei formation in the peripheral blood normo-chromatic erythrocytes (NCEs) of mice in a 14-week gavage study at dose levels of up to 60 mg/kg bw/d.

A small number of dominant lethal studies performed with acrylonitrile have reported negative results following administration by intraperitoneal injection in mice (Leonard et al., 1981), inhalation exposure of mice (Zurkov et al., 1983) and in rats following gavage administration (Working et al., 1987).

An unpublished abstract of a study of the induction of hypoxanthine-guanine phosphoribosyltransferase (Hprt) mutations in the splenic lymphocytes of mice administered acrylonitrile by gavage for 6 weeks (Walker & Ghanayem, 2003) reports positive results in normal mice at the highest dose level tested of 20 mg/kg bw/d and in CYPE2E1 knock-out mice at the highest dose level tested of 60 mg/kg bw/d (which was lethal to normal mice). Results indicate the requirement for metabolic (or enhancement by) oxidative metabolic activation of mutagenicity and also the involvement of mechanisms other than direct DNA-reactive mutagenicity. An study of Lac Z mutagenicity in the Mutamouse model using administration of acrylonitrile in the drinking water at dose levels of up to 750 ppm for 4 weeks and with a 7-week expression period reports negative findings in all tissues investigated (bone marrow, lung, splenic lymphocytes, male germ cells and brain). This assay detects point mutations, therefore indicating that the positive response in the previous study is attributable to large scale changes.

G. Carcinogenicity

The carcinogenicity of acrylonitrile has been investigated in a large number of studies in rats and mice, using oral (gavage, drinking water) and inhalation exposure. The body of literature is much too broad to summarize here, but the results of the studies indicate that acrylonitrile is a multi-site carcinogen in rodent species. However, the IARC downgraded its carcinogenicity classification of acrylonitrile to Group 2B (possibly carcinogenic to humans). This assessment was based on a consideration of the genotoxicity data, animal carcinogenicity and human epidemiological data. It was concluded that, while acrylonitrile was mutagenic in vitro, the results of studies in vivo were largely negative. The clear evidence of carcinogenicity in studies in experimental animals was not considered to be reflected in the epidemiology. The IARC concluded that, on balance, and given the largely unsupportive findings from the other epidemiology studies, the evidence of an increased incidence of lung cancer reported in exposed workers in one early study was not considered to be sufficiently strong to conclude that there was a credible association between acrylonitrile exposure and lung cancer. The earlier indications of an increased cancer risk in workers exposed to acrylonitrile were therefore not confirmed by the more recent studies, which were also considered to be more informative.

Kirman et al (2005) were able to show the link between occupational human exposure and the results of the rodent cancer assays by modelling the exposure concentrations of the metabolite (2-cyanoethylene oxide or CEO, cyanide). A cancer dose–response assessment was conducted for acrylonitrile (AN) using updated information on mechanism of action, epidemiology, toxicity, and pharmacokinetics. Although more than 10 chronic bioassays indicate that AN produces multiple tumors in rats and mice, a number of large, well-conducted epidemiology studies provide no evidence of a causal association between AN exposure and cancer mortality of any type. The epidemiological data include early industry exposures that are far higher than occur today and that approach or exceed levels found to be tumorigenic in animals. Despite the absence of positive findings in the epidemiology data, a dose–response assessment was conducted for AN based on brain tumors in rats. Mechanistic studies implicate the involvement of oxidative stress in rat brain due to CEO, but do not conclusively rule out a potential role for the direct genotoxicity of CEO. A PBPK model was used to predict internal doses (peak CEO in brain) for 12 data sets, which were pooled together to provide a consistent characterization of the dose–response relationship for brain tumor incidence in the rat. The internal dose corresponding to a 5% increase in extra risk (ED05 D 0.017 mg/L brain) and its lower confidence limit (LED05 D 0.014 mg/L brain) was used as the point of departure. The ED05 and LED05 correspond to human equivalent concentrations of 25.9 and 21.3 mg/m^3, respectively, for inhalation exposures, and to human equivalent doses of 2.1 and 1.7 mg/kg-day, respectively, for oral exposures.

H. Reproductive and Developmental Toxicity

The reproductive toxicity of acrylonitrile has been investigated in a number of studies. A two-generation inhalation toxicity study (Nemec et al., 2008) study is considered to be key to the assessment of the reproductive toxicity of acrylonitrile as it includes a comprehensive investigation of a number of relevant parameters and uses an appropriate route of exposure. Sprague-Dawley rats (25/sex/group) were exposed (whole body) by inhalation (6 hours/day) to acrylonitrile vapour at concentrations of 0, 5, 15, 45 or 90 ppm. F0 animals were exposed for 10 weeks prior to mating and throughout mating, gestation and lactation of the subsequent F1 litters. Selected F1 offspring were then similarly exposed following weaning and mated to produce F2 litters. In addition to standard reproductive indices, the study included assessment of oestrus cyclicity and sperm parameters. Postmortem investigations of parental animals included detailed histopathological assessment of the reproductive system and associated organs/tissues, detailed histopathological assessment of brain and nasal tissues. Offspring were additionally investigated for developmental ontogeny. F1 animals exposed to 90 ppm acrylonitrile showed excessive toxicity, therefore this exposure level was not investigated further. Mortality was unaffected by exposure. Systemic toxicity in exposed adult rats was limited to reduced weight gain and food consumption and increased liver weights at 45 and 90 ppm. Local toxicity (nasal irritation) was apparent during and immediately following exposure to 90 ppm; histopathological effects on the nasal tissues consistent with local irritation were also seen in some animals in all exposure groups in the F1 generation, although a NOAEC of 15 ppm for this effect was apparent in the F0 generation. The difference for this effect is attributable to the age at first exposure (8 weeks for F0, 4 weeks for F1) and may be related to differences in nasal morphology, dosimetry There was no evidence of any effect on reproductive parameters, tissues or organs of the reproductive system. Effects on offspring were limited to bodyweight effects.

Neal et al. (2009) provided a review of published and unpublished animal reproductive toxicity studies, human epidemiology studies, other non-standard investigative studies and relevant endpoints from other toxicology studies and discuss the potential of acrylonitrile to cause reproductive toxicity in exposed humans. The authors concluded that no data were seen in animal studies supporting an increased incidence of stillbirths, pre-term or post-term deliveries or maternal mortality following exposure to acrylonitrile at dose levels producing other evidence of systemic toxicity. There was very weak support in the animal data for increased infant mortality, with pup deaths increased only at the high dose level in a single generation of a three-generation reproductive toxicity study. The pup deaths may have been contributed to by decreased water intake of the dams. No evidence of increased pup mortality was seen in the two-generation inhalation reproductive toxicity study, considered to have the highest confidence level. There is no robust evidence for male-mediated toxicity, with only one equivocal study of poor quality reporting a positive result (Ahmed et al., 1992), and other studies, including a well-conducted dominant lethal study (Working et al., 1987) showing no effects. Effects on male reproductive toxicity (changes in sperm parameters or testicular degeneration) were reported in three studies, one of moderate quality

(Tandon et al., 1988) and two of very poor quality. However, several other high- or moderate-quality evaluations showed no effects on the testes or on andrology data, including the Nemec et al. (2008) inhalation reproductive toxicity study, which included the most comprehensive evaluation of these parameters.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for acrylonitrile follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011). Drinking water guidelines have been developed using the Reference dose (RfD) approach and the drinking water guidance value. Because acrylonitrile is considered carcinogenic to humans via the oral route of exposure, drinking water guidance value using the guidelines will be developed based on cancer endpoints, which traditionally do not follow this approach. For the purposes of this evaluation, given that drinking water is not a realistic route of exposure for workers, the RfD approach was adapted for acrylonitrile.

Kirman et al (2005) conducted a cancer dose–response assessment for acrylonitrile using updated information on mechanism of action, epidemiology, toxicity, and pharmacokinetics. A PBPK model was used to predict internal doses (peak CEO in brain) for 12 data sets, which were pooled together to provide a consistent characterization of the dose–response relationship for brain tumor incidence in the rat. The internal dose corresponding to a 5% increase in extra risk (ED05, 0.017 mg/L brain) and its lower confidence limit (LED05; 0.014 mg/L brain) was used as the point of departure. For this evaluation, LED05, which corresponds to 1.7 mg/kg-day for oral exposures was used as the NOAEL.

Oral Reference Dose based on Cancer Endpoint (oral RfDc)

Oral RfDc = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
NOAEL = LED05 from Kirman et. al. 2005
UF_A (interspecies variability) = 3.2
UF_H (intraspecies variability) = 6.4
UF_L (LED05 = LOAEL to NOAEL) = 10
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

The values for these uncertainty factors were described in Kirman et al. (2005) and summarized here.

- UF_A: Consistent with the UF_A value used for the oral RfD, the default value of 10 for UF_A can be treated as two specific factors of 3.2 for kinetic variation and 3.2 for dynamic variation. Because PBPK models were used to account for kinetic differences between rats and humans, thereby improving the confidence in the interspecies extrapolation, the kinetic component of UF_A was set equal to one. For the dynamic component of UF_A, a value of 3.2 was used nonlinear approach to account for potential dynamic differences between rats and humans.
- UF_H: The default value of 10 can also be treated as two specific factors of 3.2 for kinetic variation and 3.2 for dynamic variation. A factor of 2.0 was combined with the default factor of 3.2 for human variation in toxicodynamics to yield an UF_H value of 6.4 to account for the use of a PBPK model and variability analysis to address human variation for peak CEO in brain following oral exposure.
- UF_L: The authors conclude that a 5% response level reflects a fairly significant response and cannot be treated as a NOAEL for an effect of this severity. A UF_L of 10 was selected to account for the 5% increase in risk.

Applying the RfDc and the uncertainty factors results in an the oral reference dose of 0.009 mg/kg-day.

Oral RfDc = 1.7/(3.2 x 6.4 x 10 x 1 x 1) = 1.7/200 = 0.009 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfDc,

Drinking water guidance value = (oral RfDc) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.009 x 70 x 0.1)/2 = 0.03 mg/L

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

The substance does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability

· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute toxicity studies for algae, invertebrates, and fish were reviewed . The invertebrate, *Daphnia magna* appeared to be the most sensitive species with a 48 hr LC50 of 2.5 mg/L while the the EC50 for the algae, *Pseudokirchneriella subcapitata* was determined to be 10 mg/L.

Details of test results are provided below.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on acrylonitrile.

Table 2: Acute Aquatic Toxicity Studies on Acrylonitrile

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oryzias latipes	96-hr LC_{50}	5.1	1	ECHA
Daphnia magna	48-hr EC_{50}	2.5	1	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	10	1	ECHA

Chronic Studies

The 30-day LOEC to *Pimephales promela*s in a fish early life stage test was 0.34 mg/L. A NOEC of 0.17 mg/L is derived by LOEC/2. (ECHA) [Kl. score = 2].

The 21-day NOEC from a *Daphnia* reproduction test is 0.5 mg/L (ECHA) [Kl. score = 2].

The 72-hr NOEC to *Pseudokirchneriella subcapitata* is 0.95 mg/l based on growth rate (ECHA) [Kl. score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for acrylonitrile follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (0.17 mg/L), invertebrates (2.5 mg/L), and algae (10 mg/L). Results from chronic studies are available for fish (0.34 mg/L), invertebrates (0.5 mg/L), and algae (0.95 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term results studies for three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 0.17 mg/L for fish. The $PNEC_{water}$ is 0.017 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.002 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.17/1500) \times 1000 \times 0.017$
$= 0.002$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 8.511 \times 0.02$
$= 0.17$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for acrylonitrile based on the molecular connectivity index (MCI) is 8.511 L/kg (EPA, 2018).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Acrylonitrile is inherently biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 1.04, acrylonitrile does not meet the screening criteria for bioaccumulation.

The lowest chronic NOEC for acrylonitrile is >0.1 mg/L. The acute E(L)C_{50} values are >1 mg/L. Thus, acrylonitrile does not meet the criteria for toxicity.

The overall conclusion is that acrylonitrile is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable liquid – category 2
Carcinogenicity – category 1B
Acute toxicity – category 3
Acute toxicity – category 3
Specific target organ toxicity (single exposure) – category 3
Skin irritation – category 2
Eye damage – category 1
Hazardous to the aquatic environment (chronic) – category 2
Skin sensitisation – category 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison control center or doctor/physician

Skin Contact
Remove all contaminated clothing. Rinse skin with water/shower. Call a poison center or doctor/physician if you feel unwell. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice/attention

Inhalation
Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a poison center or doctor/physician

Ingestion
Do not induce vomiting. Call a physician or Poison Control Center immediately. Rinse mouth.

Notes to Physician
Causes severe eye damage. May cause allergic skin reaction. Inhalation of high vapor concentrations may cause symptoms like headache, dizziness, tiredness, nausea and vomiting: Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain or flushing. Treat symptomatically.

Medical Conditions Aggravated by Exposure
Asthma or other respiratory conditions may be aggravated by exposure to the substance

Emergency Personnel Protection
Avoid contact with – or ingestion of – the chemical. Acrylonitrile is flammable; take precautionary measures against static discharge.

B. Fire Fighting Information

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. Cool closed containers exposed to fire with water spray.

Specific Exposure Hazards
In advanced or massive fires, fire-fighting should be done from a safe distance or a protected location. Isolate for 1/2 mile in all directions if tank car or truck is involved in fire.

Vapors may form explosive mixtures with air. Vapors are heavier than air and may travel to source of ignition and flash back. Liquid may float on water.
Containers may explode when heated.

Hazardous Combustion Products: Nitrogen oxides (NOx) Carbon monoxide (CO) Carbon dioxide (CO2) Hydrogen cyanide (hydrocyanic acid)

Special Protective Equipment for Firefighters
Materials are too dangerous to health to expose fire fighters. A few whiffs of vapor could cause death or vapour or liquid could be fatal on penetrating the fire fighter's normal full protective clothing. The normal full protective clothing and breathing apparatus available to the average fire department will not provide adequate protection against inhalation or skin contact with these materials. Explosion hazard is moderate. It is flammable and explosive at normal room temperatures. Can react violently with strong acids, amines, strong alkalis. Vapors may travel considerable distance to source of ignition and flash back. Dilute solutions are also hazardous (flash point of a solution of 2 percent in water is 70F). When heated or burned, toxic hydrogen cyanide gas and oxides of nitrogen are formed. As in any fire, wear self-contained breathing apparatus and full protective gear. Thermal decomposition can lead to release of irritating gases and vapors.

C. Accidental Release Measures

Personal Precautions
Ensure adequate ventilation. Use personal protective equipment. Keep people away from and upwind of spill/leak. Evacuate unprotected persons. Remove all sources of ignition. Take precautionary measures against static discharges.

Environmental Precautions
Do not flush into surface water or sanitary sewer system.

Steps to be Taken if Material is Released or Spilled
Keep in suitable, closed containers for disposal. Soak up with inert absorbent material. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.

D. Storage and Handling

General Handling
Wear personal protective equipment. Do not get in eyes, on skin, or on clothing. Use only under a chemical fume hood. Do not breathe vapors or spray mist. Do not ingest. Keep away from open flames, hot surfaces and sources of ignition. Use only non-sparking tools. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Take precautionary measures against static discharges.

Other Handling Precautions
Respiratory protection required if ventilation is not sufficient.
Chemical is flammable and explosive at normal room temperatures.

Storage
Keep away from heat and sources of ignition. Keep away from direct sunlight. Keep container tightly closed in a dry and well-ventilated place.

Can react violently with strong acids, amines, strong alkalis. Avoid strong acids, amines, alkalis. Incompatible with strong oxidizers
(especially bromine) copper and copper alloys. Unstable, moderate hazard is possible when it is exposed to flames, strong acids, amines and alkalis.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for acrylonitrile in Australia is 2 ppm (4.3 mg/m3) as an 8-hr TWA. No STEL is listed.

Engineering Controls
Ensure adequate ventilation, especially in confined areas. Use explosion-proof electrical/ventilating/lighting/equipment. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protection Equipment
Respiratory Protection:
Use approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hand Protection:
Protective gloves; inspect before use.

Skin Protection:
Long sleeved clothing.

Eye protection:

Wear appropriate protective eyeglasses or chemical safety goggles

Other Precautions:

Explosion hazard is moderate. It is flammable and explosive at normal room temperatures.
The vapour is heavier than air and may travel along the ground; distant ignition possible.

F. TRANSPORT INFORMATION

UN Number 1093
Hazard Class 3

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

EU RAR (2004). European Union Risk Assessment Report. ACRYLONITRILE CAS No: 107-13-1 EINECS No: 203-466-5 RISK ASSESSMENT Final Report, 2004. Institute for Health and Consumer Protection, European Chemicals Bureau

Kirman, Christopher & M. Gargas & G. Marsh, D. Strother, J. Klaunig, J Collins, and R. Deskin. (2005). Cancer dose-response assessment for acrylonitrile based upon rodent brain tumor incidence: Use of epidemiologic, mechanistic, and pharmacokinetic support for nonlinearity. Regulatory toxicology and pharmacology : RTP. 43. 85-103.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ALCOHOLS, C6-12, ETHOXYLATED PROPOXYLATED

This dossier on alcohols, C6-12, ethoxylated propoxylated presents the most critical studies pertinent to the risk assessment of alcohols, C6-12, ethoxylated propoxylated in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Alcohols, C6-12, ethoxylated propoxylated

CAS RN: 68937-66-6

Molecular formula: Not available (UVCB substance)

Molecular weight: Not available (UVCB substance)

Synonyms: Alcohols, C10-16, ethoxylated propoxylated

SMILES: Not available (UVCB substance)

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure $C_{x-y}AE_n$. The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerization is indicated by the subscript (n) which indicates the average number of ethylene oxide units.

NO INFORMATION IS AVAILABLE ON ALCOHOLS, C6-12, ETHOXYLATED PROPOXYLATED. ALL INFORMATION IN THIS DOSSIER HAS BEEN READ-ACROSS FROM SIMILAR ALCOHOL ETHOXYLATES.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Alcohols, C6-C8-(Even Numbered, Linear) Ethoxylated (<2.5 EO) [CAS No. 1426148-68-6]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless, viscous liquid	1	ECHA
Melting Point	≤30°C	1	ECHA

Property	Value	Klimisch score	Reference
Boiling Point	105°C	1	ECHA
Density	0.947 g/cm^3 @ 20°C	1	ECHA
Vapor Pressure	14 hPa @ 20°C	1	ECHA
Partition coefficient (log K_{ow})	1.5 @ 23°C	1	ECHA
Water Solubility	4 g/L @ 20°C	1	ECHA
Flash Point	111°C	1	ECHA
Auto flammability	230°C	1	ECHA
Viscosity	13.3 mPA s (dynamic) @ 20°C	1	ECHA

Table 1: Overview of the Physico-chemical Properties of Alcohols, C9-11, Branched and Linear, Ethoxylated (1 – 2.5 moles ethoxylated) [CAS No. 160901-09-7, 68439-46-3]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless to light yellow liquid	2	ECHA
Melting Point	<20°C	1	ECHA
Boiling Point	260°C	2	ECHA
Density	0.94 g/cm^3 @ 20°C	1	ECHA
Vapor Pressure	Negligible	-	ECHA
Partition coefficient (log K_{ow})	3.74* @ 25°C	2	ECHA
Water Solubility	Moderately soluble	2	ECHA
Flash Point	125°C	1	ECHA
Auto flammability	311°C	1	ECHA
Viscosity	11.12 cSt @ 40°C	1	ECHA

*Weight-averaged log K_{oc} of whole substance based on normalized composition.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Alcohols, C6-12, ethoxylated propoxylated is expected to be readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

In an OECD 301 B test, degradation of alcohols, C6-8 alkyl-(even, linear), ethoxylated (<2.5 EO) [CAS No. 1426148-68-6) was 63% in 28 days. The 10-day window was met (ECHA) [Kl. score = 1].

An alcohol ethoxylate, C9-11, branched (2.5 EO) [CAS No. 169107-21-5] was readily biodegradable, as indicated by degradation of 72% in 28 days in an ultimate aerobic biodegradability (CO_2 headspace) ISO 14593 water quality test (ECHA) [Kl. score = 2].

An alcohol ethoxylate, C9-11, branched (3 EO) [CAS No. 169107-21-5] was readily biodegradable, as indicated by degradation of 101% in 28 days in an ultimate aerobic biodegradability (CO_2 headspace) ISO 14593 water quality test (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for alcohols, C6-12, ethoxylated propoxylated. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} values for surrogates of alcohols, C6-12, ethoxylated propoxylated are:

Koc for C6 linear alcohol, ethoxylated (2 EO): 10 L/kg (MCI) and 18.7 L/kg (K_{ow})

Koc for C12 linear alcohol, ethoxylated (2 EO): 279.5 L/kg (MCI) and 464 L/kg (K_{ow})

D. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of alcohols, C6-12, ethoxylated is expected to be low by the oral and dermal routes. The skin irritation rabbit studies on alcohols, C12-16, ethoxylated have shown mixed results, but human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Alcohols, ethoxylated are expected to be irritating to the eyes of rabbits. Alcohols, ethoxylated do not appear to be skin sensitisers. Repeated dose toxicity studies on

alcohol ethoxylates similar to alcohols, C12-16, ethoxylated in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic, and have a low potential for reproductive and developmental toxicity.

B. Acute Toxicity

The oral LD_{50} in rats for $C_{7\text{-}9}AE_6$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{11}AE_9$ is 1,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{9\text{-}11}AE_{2.5}$ is between 4,000 and 10,000 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{9\text{-}11}AE_8$ is 1,200 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2].

The 4-hour inhalation LC_{50} value for $C_{9\text{-}11}AE_5$ is >0.22 mg/L as a mist. The mass median aerodynamic diameter (MMAD) were 3.4 mm and 3.0 mm in the two exposure tests (HERA, 2009) [Kl. score = 2].

The acute dermal LD_{50} of $C_{7\text{-}9}AE_6$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{9\text{-}11}AE_6$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2]. An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of $C_{9\text{-}11}AE_9$ to the skin of rabbits for 4 hours under <u>semi-occlusive conditions was found to be slightly irritating</u> (HERA, 2009) [Kl. score = 2]. Application of $C_{11}AE_9$ to the skin of rabbits for 4 hours under occluded conditions was found to be slightly irritating (HERA, 2009) [Kl. score = 2]. Application of $C_{9\text{-}11}AE_6$ to the skin of rabbits for 24 hours under <u>occluded conditions was found to be severely irritating</u> (HERA, 2009) [Kl. score = 2].

Eye

Instillation of $C_{7\text{-}9}AE_{12}$ into the eyes of rabbits was minimally irritating (HERA, 2009). Instillation of $C_{9\text{-}11}AE_6$ into the eyes of rabbits was moderately to severely irritating (HERA, 2009). Instillation of $C_{7\text{-}9}AE_6$ into the eyes of one rabbit was severely irritating (HERA, 2009).

D. Sensitization

In a guinea pig maximization test, alcohols, C6-C8-(even numbered, linear)-ethoxylated (<2.5 EO) was not found to be a skin sensitizer (ECHA) [Kl. score = 1].

In a guinea pig maximization test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not found to be a skin sensitizer (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

<u>Oral</u>

Male and female CFE (SPF) rats were given in their feed 0, 125, 250, 500, 1,000, or 3,000 ppm (0, 6.25, 12.5, 25, 50, and 150 mg/kg-day) $C_{9\text{-}11}AE_6$ for 13 weeks. There was no mortality and no treatment-related clinical signs. Body weights were significantly lower in the ≥250 ppm males throughout the study; body weights of the 125 ppm males were lower for only the first half of the study. Feed consumption was lower in treated males with the change being statistically significant in the ≥1,000 ppm males. This reduction in feed consumption was thought to be a palatability issue; the feed conversion efficiency values were similar for treated and control males, and so it is not possible to attribute the reduced body weights to the toxicity of the test material alone. The female rats showed no differences in body weights and feed consumption. There were no treatment-related changes in hematology parameters, and the clinical chemistry parameters and organ weights showed no changes that were considered to be of toxicological significance. Gross pathology showed no treatment-related changes. The NOAEL for this study was considered to be 3,000 ppm, which corresponds to150 mg/kg-day (ECHA) [Kl. score = 2].

Rats were given in their feed 0, 0.04, 0.2, or 1% $C_{9\text{-}11}AE_8$ for 90 days. There were no deaths or treatment-related clinical signs during the study. There was reduced body weight gain and decreased feed consumption in the 1% animals and in the 0.2% females throughout the study. Additional statistical analysis indicated a significant decrease in mean body weight gain in the 1% females and decreased feed consumption in the 1% males and females. The reduced body weight gain of the 0.2% females was not statistically significant. The study authors considered these changes to be due to the poor palatability of the test material in the feed. Organ weights, gross and microscopic pathology were similar across groups. The NOAEL for this study is 1% in the diet, which corresponded to 400 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their feed 0, 125, 250, or 500 mg/kg $C_{10}AE_5$ for 90 days. There were no deaths or treatment-related clinical signs during the study. The only treatment-related effect noted was a slight increase in absolute liver weights, with the 500 mg/kg animals showing statistical significance. However, there were no corresponding histopathologic changes in the liver. The NOAEL is 500 mg/kg-day, the highest dose tested (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12\text{-}14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12\text{-}13}AE_{6.5}$ for two years. Body weight gain was reduced in the 1% males and ≥0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the ≥0.5% females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidence in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% $C_{9-11}AE_6$ solutions 3 days/week for 13 weeks. There were no deaths during the study and no clinical signs of toxicity. Body weights, clinical chemistry and hematology parameters, and urinalysis showed no differences between treated and control animal. The 25% animals showed a slight increase in kidney weights, although no histopathologic findings were noted in the kidney. There were no histopathologic changes that were considered to be treatment-related. The NOAEL for this study is 25% (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

F. Genotoxicity

In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). Representative results of the *in vitro* studies on alcohol ethoxylates similar to alcohols, C6-12, ethoxylated propoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{7-9}AE_2$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{7-9}AE_6$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12-15}AE_3$ or $C_{12-14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

G. Carcinogenicity

Male and female Sprague-Dawley rats were given in their diet $C_{12-13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumor incidence was observed (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

A two-generation reproductive toxicity study was conducted on $C_{9\text{-}11}AE_6$. Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% solutions of $C_{9\text{-}11}AE_6$ (0, 10, 100, or 250 mg/kg-day) 3 days/week; the F_0 and F_1 generations were treated for 119 and 133 days, respectively, before mating. There were no deaths in the F_0 generation, but there were 5 deaths in the F_1 generation (controls and treatment groups) that were not considered to be treatment-related. Animals in either generation showed no skin reactions. Body weights of the 25% F_0 and F_1 parental animals were lower during certain periods of the study; however, maternal body weights in both generations were similar across groups during the gestational and lactational periods. The organ weights in the F_0 animals were similar between treated and control animals; the F_1 parental animals showed sporadic organ weight changes but were not no toxicological significance. There were no histopathologic changes that correlated with the organ weight changes in the F_1 parental animals. Mating and fertility indices were similar across groups in both generations. There were no treatment-related effects on testicular weights, testicular pathology, serum counts and LDH-X activity toxicity in either generation. Macroscopic and microscopic evaluations of the reproductive organ showed no treatment-related effects. The NOAEL for reproductive toxicity for toxicity is 25% test concentration, which corresponded to 250 mg/kg-day, the highest dose tested (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behavior, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

A two-generation reproductive toxicity study was conducted on $C_{9\text{-}11}AE_6$. Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% solutions 3 days/week; the F_0 and F_1 generations were treated for 119 and 133 days, respectively, before mating. There were no deaths in the F_0 generation, but there were 5 deaths in the F_1 generation (controls and treatment groups) that were not considered to be treatment-related. Animals in either generation showed no skin reactions. Body weights of the 25% F_0 and F_1 parental animals were lower during certain periods of the study; however, maternal body weights in both generations were similar across groups during the gestational and lactational periods. The organ weights in the F_0 animals were similar between treated and control animals; the F_1 parental animals showed sporadic organ weight changes but were not no toxicological significance. There were no histopathologic changes that correlated with the organ weight changes in the F_1 parental animals. There was no effect on litter size, survival index, sex ratio, or body weights of the pups in either the F_1 or F_2 generation. The NOAEL for developmental toxicity is 25% test concentration, which corresponded to 250 mg/kg-day, the highest dose tested (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behavior, appearance and

survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean fetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE_6$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live fetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for alcohols, C6-12 ethoxylated propoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A two-year dietary study in rats has been conducted on $C_{12-13}AE_{6.5}$ (HERA, 2009). The NOAEL from this study is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for alcohols, C6-12 ethoxylated propoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

The alcohol ethoxylate $C_{12\text{-}13}AE_{6.5}$ was not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Alcohols, C6-12, ethoxylated propoxylated does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Alcohol, C6-12, ethoxylated propoxylated is expected to have moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC, 2000), the toxicity data was normalized for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalized to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 mg/L.

Freshwater crustaceans: 2 species, 590 to 860 mg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 mg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 mg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 mg/L, although replication was insufficient to meet OECD (1992) requirements. Normalized data were 380, 380, 320, and 1,520 mg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

$PNEC_{water}$: The ANZECC water quality guideline (2000) for freshwater is: **"A high reliability trigger value of 140 mg/L was derived for AE (normalized data) using the statistical distribution method with 95% protection."**

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ values are 0.03 to 0.87 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.37/1500) \times 1000 \times 0.14$
$= 0.03$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (9.28/1500) \times 1000 \times 0.14$
$= 0.87$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 18.7 \times 0.02$
$= 0.37$

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 464 \times 0.02$
$= 9.28$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for alcohols, C6-12, ethoxylated propoxylated based on K_{ow} values range from 18.7 to 464 L/kg (see section III.C).

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Alcohols, C6-12, ethoxylated propoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes alcohols, C12-16, ethoxylated) have been reported to range from <5 to 387.5. Thus, alcohols, C6-12, ethoxylated propoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, alcohols, C6-12, ethoxylated propoxylated do not meet the criteria for toxicity.

Therefore, alcohols, C6-12, ethoxylated propoxylated is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Irritant Category 2
Aquatic Chronic Toxicity Category 3

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions
Prevent from entering sewers, waterways, or low area

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for alcohols, C6-12, ethoxylated propoxylated.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Wear respiratory protection if ventilation is inadequate.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Chemical safety goggles.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Alcohols, C6-12, ethoxylated propoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Gingell, R., and Lu, C.C. (1991). Acute, subchronic, and reproductive toxicity of a linear alcohol ethoxylate surfactant in the rat. J. Am. College Toxicol. 10: 477-486.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ALCOHOLS, C10-16, ETHOXYLATED PROPOXYLATED

This dossier on alcohols, C10-16, ethoxylated propoxylated presents the most critical studies pertinent to the risk assessment of alcohols, C10-16, ethoxylated propoxylated in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009), from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Alcohols, C10-16, ethoxylated propoxylated

CAS RN: 69227-22-1

Molecular formula: Not available (UVCB substance)

Molecular weight: Not available (UVCB substance)

Synonyms: Alcohols, C10-16, ethoxylated propoxylated

SMILES: Not available (UVCB substance)

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure $C_{x\text{-}y}AE_n$. The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerization is indicated by the subscript (n) which indicates the average number of ethylene oxide units.

NO INFORMATION IS AVAILABLE ON ALCOHOLS, C10-16, ETHOXYLATED PROPOXYLATED. ALL INFORMATION IN THIS DOSSIER HAS BEEN READ-ACROSS FROM SIMILAR ALCOHOL ETHOXYLATES.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Alcohols, C12-15, Ethoxylated (1 to 2.5 moles ethoxylated) [CAS No. 68131-39-5]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancid odor*	2	ECHA
Melting Point	7.22°C	2	ECHA
Boiling Point	ca. 287°C	1	ECHA
Density	0.926 g/cm^3 @ 15.56°C	1	ECHA
Vapor Pressure	Negligible	-	ECHA
Partition coefficient (log K_{ow})	5.06* @ 25°C	2	ECHA
Water Solubility	7 – 63 mg/L @ 25°C	2	ECHA
Flash Point	165.56°C	2	ECHA
Auto flammability	235°C	2	ECHA
Viscosity	28.1 mPA s (dynamic) @ 20°C	2	ECHA

*Based on alcohols, C12-14, ethoxylated (1 to 2.5 EO) [CAS No. 68439-50-9]

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Alcohols, C10-16, ethoxylated propoxylated is expected to be readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

An alcohol ethoxylate, C9-11, branched (2.5 EO) [CAS No. 169107-21-5] was readily biodegradable, as indicated by degradation of 72% in 28 days in an ultimate aerobic biodegradability (CO_2 headspace) ISO 14593 water quality test (ECHA) [Kl. score = 2].

An alcohol ethoxylate, C9-11, branched (3 EO) [CAS No. 169107-21-5] was readily biodegradable, as indicated by degradation of 101% in 28 days in an ultimate aerobic biodegradability (CO_2 headspace) ISO 14593 water quality test (ECHA) [Kl. score = 2].

Alcohols, C12-15, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 72% in 28 days, but failed the 10-day window (ECHA) [Kl. score = 1].

An alcohol, C12-15, ethoxylated (7 EO) was readily biodegradable, as indicated by degradation of 80 to 88% in 28 days when tested using a shake-flask CO_2-evolution test method (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for alcohols, C10-16, ethoxylated propoxylated. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} values for surrogates of alcohols, C10-16, ethoxylated propoxylated are:

Koc for C10 linear alcohol, ethoxylated (2 EO): 84.1 L/kg (MCI) and 133.2 L/kg (K_{ow})

Koc for C16 linear alcohol, ethoxylated (2 EO): 3,083 L/kg (MCI) and 5,706 L/kg (K_{ow})

D. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary
The substance displays a relatively low order of acute toxicity.

Tests with similar substances indicate irritation in animal evaluations while human patch tests suggest relatively minimal irritation post exposure. Additionally, the weight of evidence suggests ethoxylates are likely to be irritating to the eyes. Ethoxylates are not expected to be sensitizers.

While no inhalation studies were found, oral and dermal repeat dose studies with similar substances do not indicate significant toxicity.

Similar substances do not demonstrate genotoxicity according to in vitro and in vivo studies and there was no evidence for any in vivo carcinogenic activity after long term oral dosing.

Relatively high NOAELs obtained from 2-generation oral dosing do not support a concluson that the ethoxylates are reproductively and developmentally toxic.

B. Acute Toxicity

The oral LD_{50} in rats for $C_{11}AE_9$ is 1,100 mg/kg (HERA, 2009) [Kl. score = 2].
The oral LD_{50} in rats for $C_{9\text{-}11}AE_{2.5}$ is between 4,000 and 10,000 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{9\text{-}11}AE_8$ is 1,200 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_7$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2].

The 4-hour inhalation LC_{50} value for $C_{9\text{-}11}AE_5$ is >0.22 mg/L as a mist. The mass median aerodynamic diameters (MMAD) were 3.4 mm and 3.0 mm in the two exposure studies (HERA, 2009) [Kl. score = 2].

The acute dermal LD_{50} of $C_{9\text{-}11}AE_6$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2]. An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_7$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of $C_{9\text{-}11}AE_9$ to the skin of rabbits for 4 hours under semi-occlusive conditions was found to be slightly irritating (HERA, 2009) [Kl. score = 2]. Application of $C_{11}AE_9$ to the skin of rabbits for 4 hours under occluded conditions was found to be slightly irritating (HERA, 2009) [Kl. score = 2]. Application of $C_{9\text{-}11}AE_6$ to the skin of rabbits for 24 hours under occluded conditions was found to be severely irritating (HERA, 2009) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2]. Application of 0.5 mL isotridecanol, branched, ethoxylated (3-4 EO) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2]. Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2]. Application of 0.5 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL alcohols C12-13, branched and linear, <2.5 EO to the skin of rabbits for 4 hours under occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or edema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2]. Nonetheless, current classification according to ECHA recommends classification as an irritant.

Eye

Instillation of $C_{9\text{-}11}AE_6$ into the eyes of rabbits was moderately to severely irritating (HERA, 2009).

Instillation of 0.1 mL isotridecanol, ethoxylated (3 EO) (CAS No. 69011-36-5) into the eyes of rabbits was severely irritating. The means of the 24, 48, and 72 hour scores were: 1.6 for corneal opacity; 0.6 for iridial lesions; 2.2 for conjunctival redness; and 0.7 for chemosis. The effects were not fully reversible within 21 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL isotridecanol, branched, ethoxylated (3-4 EO) (CAS No. 24938-91-8) into the eyes of rabbits was severely irritating. The means of the 24, 48, and 72 hour scores were: 1.0 for corneal opacity; 0.1 for iridial lesions; 1.7 for conjunctival redness; and 0.6 for chemosis. The effects were not fully reversible within 8 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL alcohols C12-13, branched and linear, <2.5 EO (CAS No. 160901-19-9) into the eyes of rabbits was not irritating. The means of the 24, 48, and 72 hour scores were: 0.00 for corneal opacity; 0.00 for iridial lesions; 0.83 for conjunctival redness; and 0.50 for chemosis (ECHA) [Kl. score = 2].

Instillation of 0.1 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) into the eyes of rabbits was not irritating. The means of the 24, 48, and 72 hour scores were: 0.00 for all endpoints (ECHA) [Kl. score = 2].

D. Sensitization

In a guinea pig maximization test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitizer (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

Male and female CFE (SPF) rats were given in their feed 0, 125, 250, 500, 1,000, or 3,000 ppm (0, 6.25, 12.5, 25, 50, and 150 mg/kg-day) $C_{9\text{-}11}AE_6$ for 13 weeks. There was no mortality and no treatment-related clinical signs. Body weights were significantly lower in the $\geq$250 ppm males throughout the study; body weights of the 125 ppm males were lower for only the first half of the study. Feed consumption was lower in treated males with the change being statistically significant in the $\geq$1,000 ppm males. This reduction in feed consumption was thought to be related to palatability; the feed conversion efficiency values were similar for treated and control males, and so it is not possible to attribute the reduced body weights to the toxicity of the test material alone. The female rats showed no differences in body weights and feed consumption. There were no treatment-related changes in hematology parameters, and the clinical chemistry parameters and organ weights showed no changes that were considered to be of toxicological significance. Gross pathology showed no treatment-related changes. The NOAEL for this study was considered to be 3,000 ppm, which corresponds to150 mg/kg-day (ECHA) [Kl. score = 2].

Rats were given in their feed 0, 0.04, 0.2, or 1% $C_{9\text{-}11}AE_8$ for 90 days. There were no deaths or treatment-related clinical signs during the study. There was reduced body weight gain and decreased feed consumption in the 1% animals and in the 0.2% females throughout the study. Additional statistical analysis indicated a significant decrease in mean body weight gain in the

1% females and decreased feed consumption in the 1% males and females. The reduced body weight gain of the 0.2% females was not statistically significant. The study authors considered these changes to be due to the poor palatability of the test material in the feed. Organ weights, gross and microscopic pathology were similar across groups. The NOAEL for this study is 1% in the diet, which corresponded to 400 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their feed 0, 125, 250, or 500 mg/kg $C_{10}AE_5$ for 90 days. There were no deaths or treatment-related clinical signs during the study. The only treatment-related effect noted was a slight increase in absolute liver weights, with the 500 mg/kg animals showing statistical significance. However, there were no corresponding histopathologic changes in the liver. The NOAEL is 500 mg/kg-day, the highest dose tested (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125, 0.25, 0.5 or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12\text{-}14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12\text{-}13}AE_{6.5}$ for two years. Body weight gain was reduced in the 1% males and $\geq$0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the $\geq$0.5% females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidence in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% $C_{9\text{-}11}AE_6$ solutions 3 days/week for 13 weeks. There were no deaths during the study and no clinical signs of toxicity. Body weights, clinical chemistry and hematology parameters, and urinalysis showed no differences between treated and control animal. The 25% animals showed a slight increase in kidney weights, although no histopathologic findings were noted in the kidney. There were no

histopathologic changes that were considered to be treatment-related. The NOAEL for this study is 25% (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

F. Genotoxicity

In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to alcohols C10-16, ethoxylated propoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009 [Kl. score = 2].

G. Carcinogenicity

Male and female Sprague-Dawley rats were given in their diet $C_{12\text{-}13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumor incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behavior and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumor incidence (HERA, 2009) [Kl. score = 2]

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

A two-generation reproductive toxicity study was conducted on $C_{9\text{-}11}AE_6$. Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% solutions of $C_{9\text{-}11}AE_6$ (0, 10, 100, or 250 mg/kg-day) 3 days/week; the F_0 and F_1 generations were treated for 119 and 133 days, respectively, before mating. There were no deaths in the F_0 generation, but there were 5 deaths in the F_1 generation (controls and treatment groups) that were not considered to be treatment-related. Animals in either generation showed no skin reactions. Body weights of the 25% F_0 and F_1 parental animals were lower during certain periods of the study; however, maternal body weights in both generations were similar across groups during the gestational and lactational periods. The organ weights in the F_0 animals were similar between treated and control animals; the F_1 parental animals showed sporadic organ weight changes but were not no toxicological significance. There were no histopathologic changes that correlated with the organ weight changes in the F_1 parental animals. Mating and fertility indices were similar across groups in both generations. There were no treatment-related effects on testicular weights, testicular pathology, serum counts and LDH-X activity toxicity in either generation. Macroscopic and microscopic evaluations of the reproductive organ showed no treatment-related effects. The NOAEL for reproductive toxicity for toxicity is 25% test concentration, which corresponded to 250 mg/kg-day, the highest dose tested (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behavior, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0, 0.05, 0.1 or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behavior or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

A two-generation reproductive toxicity study was conducted on $C_{9\text{-}11}AE_6$. Male and female F344 rats were given dermal applications of 0, 1, 10, or 25% solutions 3 days/week; the F_0 and F_1 generations were treated for 119 and 133 days, respectively, before mating. There were no

deaths in the F_0 generation, but there were 5 deaths in the F_1 generation (controls and treatment groups) that were not considered to be treatment-related. Animals in either generation showed no skin reactions. Body weights of the 25% F_0 and F_1 parental animals were lower during certain periods of the study; however, maternal body weights in both generations were similar across groups during the gestational and lactational periods. The organ weights in the F_0 animals were similar between treated and control animals; the F_1 parental animals showed sporadic organ weight changes but were not no toxicological significance. There were no histopathologic changes that correlated with the organ weight changes in the F_1 parental animals. There was no effect on litter size, survival index, sex ratio, or body weights of the pups in either the F_1 or F_2 generation. The NOAEL for developmental toxicity is 25% test concentration, which corresponded to 250 mg/kg-day, the highest dose tested (Gingell and Lu, 1991; ECHA) [Kl. score = 2].

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behavior, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean fetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE_6$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live fetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for C10-16, ethoxylated propoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A two-year dietary study in rats has been conducted on $C_{12\text{-}13}AE_{6.5}$ (HERA, 2009). The NOAEL from this study is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for C10-16, ethoxylated propoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

The alcohol ethoxylates $C_{12-13}AE_{6.5}$ and $C_{14-15}AE_7$ were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Alcohols, C10-16, ethoxylated propoxylated does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Alcohol, C10-16, ethoxylated propoxylated is expected to have moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC, 2000), the toxicity data was normalized for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalized to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 mg/L.

Freshwater crustaceans: 2 species, 590 to 860 mg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 mg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 mg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 mg/L, although replication was insufficient to meet OECD (1992) requirements. Normalized data were 380, 380, 320, and 1,520 mg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

$PNEC_{water}$: The ANZECC water quality guideline (2000) for freshwater is: **"A high reliability trigger value of 140 mg/L was derived for AE (normalized data) using the statistical distribution method with 95% protection."**

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ values are 0.25 to 10.7 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (2.66/1500) \times 1000 \times 0.14$
$= 0.25$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (114.12/1500) x 1000 x 0.14
= 10.65

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
= 133 x 0.02
= 2.66

$Kp_{soil} = K_{oc} \times f_{oc}$
= 5,706 x 0.02
= 114.12

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for alcohols, C10 - 16, ethoxylated propoxylated based on K_{ow} values range from 133 to 5,706 L/kg (see section III.C).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Alcohols, C10-16, ethoxylated propoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes alcohols, C12-16, ethoxylated) have been reported to range from <5 to 387.5. Thus, alcohols, C10-16, ethoxylated propoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, alcohols, C10-16, ethoxylated propoxylated do not meet the criteria for toxicity.

The overall conclusion is that alcohols, C10-16, ethoxylated propoxylated is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Irritant Category 2
Aquatic Chronic Toxicity Category 3

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions

Prevent from entering sewers, waterways, or low area

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage and Handling

General Handling
Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for C10-16, ethoxylated propoxylated.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection:
Wear respiratory protection if ventilation is inadequate.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Chemical safety goggles.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Alcohols, C10-16 ethoxylated propoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Gingell, R., and Lu, C.C. (1991). Acute, subchronic, and reproductive toxicity of a linear alcohol ethoxylate surfactant in the rat. J. Am. College Toxicol. 10: 477-486.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ALCOHOLS, C12-15, ETHOXYLATED

This dossier on alcohols, C12-15, ethoxylated presents the most critical studies pertinent to the risk assessment of alcohols, C12-15, ethoxylated in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA).. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Alcohols, C12-15, ethoxylated

CAS RN: 68131-39-5

Molecular formula: (C2H4O)1-3(CH2)10-13C2H6O

Molecular weight: Not available

Synonyms: Alcohols, C12-15, ethoxylated

SMILES: Not available

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure $C_{x-y}AE_n$. The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerization is indicated by the subscript (n) which indicates the average number of ethylene oxide units. Alcohols, C12-15, ethoxylated (CAS No. 68131-39-5) has an average number of 1 to 2.5 moles of ethylene oxide units.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Alcohols, C12-15, Ethoxylated (1 to 2.5 moles ethoxylated)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancid odor*	2	ECHA
Melting Point	7.22°C	2	ECHA
Boiling Point	ca. 287°C	1	ECHA

Property	Value	Klimisch score	Reference
Density	0.926 g/cm^3 @ 15.56^{o}C	1	ECHA
Vapor Pressure	Negligible	-	ECHA
Partition coefficient (log K_{ow})	5.06* @ 25°C	2	ECHA
Water Solubility	7 – 63 mg/L @ 25°C	2	ECHA
Flash Point	165.56^{o}C	2	ECHA
Auto flammability	235°C	2	ECHA
Viscosity	28.1 mPA s (dynamic) @ 20°C	2	ECHA

*Based on alcohols, C12-14, ethoxylated (1 to 2.5 EO) [CAS No. 68439-50-9]
**Weight-averaged log K_{oc} of whole substance based on normalized composition

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Alcohols, C12-15, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

Alcohols, C12-15, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 72% in 28 days, but failed the 10-day window (ECHA) [Kl. score = 1].

An alcohol, C12-15, ethoxylated (7 EO) degraded 80 to 88% in 28 days when tested using a shake-flask CO_2-evolution test method (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for alcohols, C12-15, ethoxylated. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} values for surrogates of alcohols, C12-15, ethoxylated are:

C12 linear alcohol, ethoxylated (2 EO): 279.5 L/kg (MCI) and 464.2 L/kg (K_{ow})

C15 linear alcohol, ethoxylated (2 EO): 1,691 L/kg (MCI) and 3,018 L/kg (K_{ow})

D. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of alcohols, C12-15, ethoxylated is low by the oral and dermal routes. The skin irritation rabbit studies on alcohols, C12-15, ethoxylated have shown mixed results, but human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Alcohols, C12-15, ethoxylated is expected to be irritating to the eyes of rabbits. Alcohols, C12-15, ethoxylated is not a skin sensitizer. Repeated dose toxicity studies on alcohol ethoxylates similar to alcohols, C12-15, ethoxylated in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic, and have a low potential for reproductive and developmental toxicity.

B. Acute Toxicity

No acute toxicity studies are available on alcohols, C12-15, ethoxylated.

The oral LD_{50} in rats for $C_{12\text{-}15}AE_3$ is >5,000 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_7$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}15}AE_{11}$ is >2,000 mg/kg in males and between 1,000 and 2,000 mg/kg in females (HERA, 2009) [Kl. score = 2]. The oral LD_{50} values in rats for $C_{14\text{-}15}AE_{13}$ in two separate studies are 1,100 and 1,000 mg/kg (HERA, 2009) [Kl. score = 2]. The relative number of EO units, but not the carbon chain length, appears to influence acute oral toxicity (HERA, 2009).

An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_7$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or edema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2].

Eye

Most alcohol ethoxylates tested as the undiluted neat test material are moderately to severely irritating to the eyes of rabbits, with an eye irritation index (EII) ranging from >25 to 50 (HERA, 2009). The alcohol ethoxylates $C_{12\text{-}14}AE_3$, $C_{12\text{-}14}AE_6$, $C_{13}AE_6$, and $C_{12\text{-}14}AE_{10}$ were found to be moderately to severely irritating to the eyes of rabbits (HERA, 2009). In another study, $C_{12\text{-}15}AE_{11}$ was considered moderately to severely irritating to the eyes of rabbits (HERA, 2009).

Some alcohol ethoxylates were reported to be practically or minimally irritating to the eyes of rabbits with EII scores of 0.5 to 15. These alcohol ethoxylates include: $C_{12\text{-}15}AE_3$, $C_{14\text{-}15}AE_7$, $C_{12\text{-}14}AE_{15}$, $C_{14\text{-}15}AE_{18}$, and $C_{13}AE_{20}$ (HERA, 2009).

D. Sensitization

No sensitization studies are available on alcohols, C12-15, ethoxylated.

In a guinea pig maximization test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitizer (ECHA) [Kl. score = 2].

In a guinea pig maximization tests, $C_{12\text{-}15}AE_3$, $C_{12\text{-}15}AE_7$, and $C_{14\text{-}15}AE_7$ were not considered skin sensitizers (HERA, 2009) [Kl. scores = 2].

E. Repeated Dose Toxicity

Oral

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125, 0.25, 0.5 or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12\text{-}14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups,

suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female Wistar rats given in their diet 0, 300, 1,000, 3,000, and 10,000 ppm $C_{14\text{-}15}AE_7$ for 90 days. There were no deaths during the study. Mean body weights and feed were lower in 10,000 ppm males and the 3,000 ppm females. Feed consumption was lower in the 10,000 ppm animals and the 3,000 ppm females. Relative liver weights were increased in the $\geq$3,000 ppm animals, and relative spleen weights were increased in the 10,000 ppm males. Clinical chemistry changes were noted in the 10,000 ppm group and consisted of significantly higher urea, chloride and potassium levels in males; significantly higher urea, chloride and cholesterol in females. Increased total leucocytes and lymphocytes were seen in the 10,000 ppm animals and in the 3,000 ppm males. The 10,000 ppm females showed lower numbers of neutrophils; mean cell volume and mean cell hemoglobin were identified in one or both sexes fed in the $\geq$3,000 ppm dose groups. In the 1,000 ppm females, there were minor, but statistically significant changes in the liver and kidney weights and plasma urea concentration; these effects were considered to be of no toxicological significance. Histopathologic examination showed no treatment-related effects at any dose level. The NOAEL for this study is 1,000 ppm in the diet, which corresponded to 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5, or 1% $C_{14\text{-}15}AE_7$ for 90 days. Body weights, food intake, organ weights, and hematology and clinical chemistry parameters were similar across groups. The NOAEL for this study is 1% in the diet, which corresponded to 700 and 785 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12\text{-}13}AE_{6.5}$ or $C_{14\text{-}15}AE_7$ for two years. Body weight gain was reduced in the 1% males and $\geq$0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the $\geq$0.5% females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidences in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female CR rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. Relative liver, kidney, heart, and thyroid/parathyroid gland weights were increased in the 1% dietary group at study termination. Histopathological examination showed a dose-related increase in the incidence of focal myocarditis at the 12-month time point, but not at the end of the study at two years. The NOAEL for this study was considered to be 0.5% in the diet, which corresponded to 162 and 190 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
No adequate studies are available.

F. Genotoxicity

In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to alcohols, C12-15, ethoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009 [Kl. score = 2].

G. Carcinogenicity

No studies are available on alcohols, C12-15, ethoxylated.

Male and female Sprague-Dawley rats were given in their diet $C_{12\text{-}13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumor

incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behavior and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumor incidence (HERA, 2009) [Kl. score = 2].

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

No studies are available on alcohols, C12-15, ethoxylated.

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behavior, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0, 0.05, 0.1 or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behavior or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

No studies are available on alcohols, C12-15, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behavior, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less

weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean fetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live fetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for alcohols, C12-15, ethoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Two-year dietary studies in rats have been conducted on alcohol ethoxylates $C_{12-13}AE_{6.5}$ and $C_{14-15}AE_7$ (HERA, 2009). The lowest NOAEL from these studies is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for alcohols, C12-15, ethoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

Several alcohol ethoxylates similar to alcohols, C12-16, ethoxylated were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Alcohols, C12-15, ethoxylated does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Alcohol, C12-15, ethoxylated has moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC, 2000), the toxicity data was normalized for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalized to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 mg/L.

Freshwater crustaceans: 2 species, 590 to 860 mg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 mg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 mg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 mg/L, although replication was insufficient to meet OECD (1992) requirements. Normalized data were 380, 380, 320, and 1,520 mg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

$PNEC_{water}$: The ANZECC water quality guideline (2000) for freshwater is: **"A high reliability trigger value of 140 mg/L was derived for AE (normalized data) using the statistical distribution method with 95% protection."**

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ values are 0.9 to 5.6 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (9.28/1500) \times 1000 \times 0.14$
$= 0.87$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (60.36/1500) \times 1000 \times 0.14$
$= 5.63$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 464 \times 0.02$
$= 9.28$

$Kp_{soil} = K_{oc} \times f_{oc}$

$= 3,018 \times 0.02$
$= 60.36$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for alcohols, C12-15, ethoxylated based on K_{ow} values range from 464 to 3,018 L/kg (see section III.C).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Alcohols, C12-15, ethoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes alcohols, C12-15, ethoxylated) have been reported to range from <5 to 387.5. Thus, alcohols, C12-15, ethoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, alcohols, C12-15, ethoxylated do not meet the criteria for toxicity.

Thus, alcohols, C12-15, ethoxylated is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]
Eye Irritant Category 2
Aquatic Chronic Toxicity Category 3

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions
Prevent from entering sewers, waterways, or low area

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for isotridecanol, ethoxylated.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Wear respiratory protection if ventilation is inadequate.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Chemical safety goggles.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Isotridecanol, ethoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ALCOHOLS, C12-16, ETHOXYLATED

This dossier on alcohols, C12-16, ethoxylated presents the most critical studies pertinent to the risk assessment of alcohols, C12-16, ethoxylated in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Alcohols, C12-16, ethoxylated

CAS RN: 68551-12-2

Molecular formula: Not available (UVCB substance)

Molecular weight: Not available (UVCB substance)

Synonyms: Alcohols, C12-16, ethoxylated

SMILES: Not available (UVCB substance)

Alcohol ethoxylates (AE) are a class of non-ionic surfactant polymers that have the basic structure $C_{x\text{-}y}AE_n$. The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerization is indicated by the subscript (n) which indicates the average number of ethylene oxide units.

II. PHYSICAL AND CHEMICAL PROPERTIES

No information is available on alcohols, C12-16, ethoxylated. Thus, data were read across from a similar substance, alcohols, C12-15, ethoxylated, as shown below.

Table 1: Overview of the Physico-chemical Properties of Alcohols, C12-15, Ethoxylated (1 to 2.5 moles ethoxylated)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancid odor*	2	ECHA
Melting Point	7.22°C	2	ECHA

Property	Value	Klimisch score	Reference
Boiling Point	ca. 287°C	1	ECHA
Density	0.926 g/cm^3 @ 15.56°C	1	ECHA
Vapor Pressure	Negligible	-	ECHA
Partition coefficient (log K_{ow})	5.06* @ 25°C	2	ECHA
Water Solubility	7 – 63 mg/L @ 25°C	2	ECHA
Flash Point	165.56°C	2	ECHA
Auto flammability	235°C	2	ECHA
Viscosity	28.1 mPA s (dynamic) @ 20°C	2	ECHA

*Based on alcohols, C12-14, ethoxylated (1 to 2.5 EO) [CAS No. 68439-50-9]
**Weight-averaged log K_{oc} of whole substance based on normalized composition

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Alcohols, C12-16, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

No studies are available on alcohol, C12-16, ethoxylated.

Alcohols, C12-15, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 72% in 28 days, but failed the 10-day window (ECHA) [Kl. score = 1].

An alcohol, C12-15, ethoxylated (7 EO) degraded 80 to 88% in 28 days when tested using a shake-flask CO_2-evolution test method (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for alcohols, C12-16, ethoxylated. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} values for surrogates of alcohols, C12-16, ethoxylated are:

Koc for C12 linear alcohol, ethoxylated (2 EO): 279.5 L/kg (MCI) and 464.2 L/kg (K_{ow})

Koc for C16 linear alcohol, ethoxylated (2 EO): 3,083 L/kg (MCI) and 5,706 L/kg (K_{ow})

D. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of alcohols, C12-16, ethoxylated is low by the oral and dermal routes. The skin irritation rabbit studies on alcohols, C12-16, ethoxylated have shown mixed results, but human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Alcohols, C12-16, ethoxylated is expected to be irritating to the eyes of rabbits. Alcohols, C12-16, ethoxylated is not a skin sensitizer. Repeated dose toxicity studies on alcohol ethoxylates similar to alcohols, C12-16, ethoxylated in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic, and have a low potential for reproductive and developmental toxicity.

B. Acute Toxicity

No acute toxicity studies are available on alcohols, C12-16, ethoxylated.

The oral LD_{50} in rats for $C_{12\text{-}15}AE_3$ is >5,000 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_7$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}15}AE_{11}$ is >2,000 mg/kg in males and between 1,000 and 2,000 mg/kg in females (HERA, 2009) [Kl. score = 2]. The oral LD_{50} values in rats for $C_{14\text{-}15}AE_{13}$ in two separate studies are 1,100 and 1,000 mg/kg (HERA, 2009) [Kl. score = 2]. The relative number of EO units, but not the carbon chain length, appears to influence acute oral toxicity (HERA, 2009).

Acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_7$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or edema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2]. Nonetheless, the substance is classified by ECHA as an irritant (see Section IX).

Eye

Most alcohol ethoxylates tested as the undiluted neat test material are moderately to severely irritating to the eyes of rabbits, with an eye irritation index (EII) ranging from >25 to 50 (HERA, 2009). The alcohol ethoxylates $C_{12\text{-}14}AE_3$, $C_{12\text{-}14}AE_6$, $C_{13}AE_6$, and $C_{12\text{-}14}AE_{10}$ were found to be moderately to severely irritating to the eyes of rabbits (HERA, 2009). In another study, $C_{12\text{-}15}AE_{11}$ was considered moderately to severely irritating to the eyes of rabbits (HERA, 2009).

Some alcohol ethoxylates were reported to be practically or minimally irritating to the eyes of rabbits with EII scores of 0.5 to 15. These alcohol ethoxylates include: $C_{12\text{-}15}AE_3$, $C_{14\text{-}15}AE_7$, $C_{12\text{-}14}AE_{15}$, $C_{14\text{-}15}AE_{18}$, and $C_{13}AE_{20}$ (HERA, 2009).

D. Sensitization

No sensitization studies are available on alcohols, C12-16, ethoxylated.

In a guinea pig maximization test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitizer (ECHA) [Kl. score = 2].

In a guinea pig maximization tests, $C_{12\text{-}15}AE_3$, $C_{12\text{-}15}AE_7$, and $C_{14\text{-}15}AE_7$ were not considered skin sensitizers (HERA, 2009) [Kl. scores = 2].

E. Repeated Dose Toxicity

Oral
No repeated dose toxicity studies are available on alcohols, C12-16, ethoxylated. Data for similar ethoxylates are presented below.

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125, 0.25, 0.5 or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the $\geq$0.5% male rats and $\geq$0.25% females. Histopathologic examination showed hepatocytic enlargement in the $\geq$0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels.

The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12-14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female Wistar rats given in their diet 0, 300, 1,000, 3,000, and 10,000 ppm $C_{14-15}AE_7$ for 90 days. There were no deaths during the study. Mean body weights and feed were lower in 10,000 ppm males and the 3,000 ppm females. Feed consumption was lower in the 10,000 ppm animals and the 3,000 ppm females. Relative liver weights were increased in the ≥3,000 ppm animals, and relative spleen weights were increased in the 10,000 ppm males. Clinical chemistry changes were noted in the 10,000 ppm group and consisted of significantly higher urea, chloride and potassium levels in males; significantly higher urea, chloride and cholesterol in females. Increased total leucocytes and lymphocytes were seen in the 10,000 ppm animals and in the 3,000 ppm males. The 10,000 ppm females showed lower numbers of neutrophils; mean cell volume and mean cell hemoglobin were identified in one or both sexes fed in the ≥3,000 ppm dose groups. In the 1,000 ppm females, there were minor, but statistically significant changes in the liver and kidney weights and plasma urea concentration; these effects were considered to be of no toxicological significance. Histopathologic examination showed no treatment-related effects at any dose level. The NOAEL for this study is 1,000 ppm in the diet, which corresponded to 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5, or 1% $C_{14-15}AE_7$ for 90 days. Body weights, food intake, organ weights, and hematology and clinical chemistry parameters were similar across groups. The NOAEL for this study is 1% in the diet, which corresponded to 700 and 785 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12-13}AE_{6.5}$ or $C_{14-15}AE_7$ for two years. Body weight gain was reduced in the 1% males and ≥0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the ≥0.5% females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidence in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female CR rats were given in their diet $C_{14-15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. Relative liver, kidney, heart, and thyroid/parathyroid gland weights were increased in the 1% dietary group at study termination. Histopathological examination showed a dose-related increase in the incidence of focal myocarditis at the 12-month time point, but not at the end of

the study at two years. The NOAEL for this study was considered to be 0.5% in the diet, which corresponded to 162 and 190 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
No adequate studies are available.

F. Genotoxicity

In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to alcohols, C12-16, ethoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009 [Kl. score = 2].

G. Carcinogenicity

No studies are available on alcohols, C12-16, ethoxylated. Therefore, data from similar substances are presented below.

Male and female Sprague-Dawley rats were given in their diet $C_{12\text{-}13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumor incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behavior and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumor incidence (HERA, 2009) [Kl. score = 2].

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

No studies are available on alcohols, C12-16, ethoxylated.

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behavior, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0, 0.05, 0.1 or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behavior or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

No studies are available on alcohols, C12-16, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behavior, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean fetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live fetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for alcohols, C12-16, ethoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Two-year dietary studies in rats have been conducted on alcohol ethoxylates $C_{12-13}AE_{6.5}$ and $C_{14-15}AE_7$ (HERA, 2009). The lowest NOAEL from these studies is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for alcohols, C12-16, ethoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

Several alcohol ethoxylates similar to alcohols, C12-16, ethoxylated were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Alcohols, C12-16, ethoxylated does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Alcohol, C12-16, ethoxylated has moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC, 2000), the toxicity data was normalized for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalized to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 mg/L.

Freshwater crustaceans: 2 species, 590 to 860 mg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 mg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 mg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 mg/L, although replication was insufficient to meet OECD (1992) requirements. Normalized data were 380, 380, 320, and 1,520 mg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

$PNEC_{water}$: The ANZECC water quality guideline (2000) for freshwater is: **"A high reliability trigger value of 140 mg/L was derived for AE (normalized data) using the statistical distribution method with 95% protection."**

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ values are 0.9 to 10.7 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (9.28/1500) \times 1000 \times 0.14$
$= 0.87$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (114.12/1500) \times 1000 \times 0.14$
$= 10.65$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 464 \times 0.02$
$= 9.28$

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 5{,}706 \times 0.02$
$= 114.12$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for alcohols, C12-16, ethoxylated based on K_{ow} values range from 464 to 5,706 L/kg (see section III.C).

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Alcohols, C12-16, ethoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes alcohols, C12-16, ethoxylated) have been reported to range from <5 to 387.5. Thus, alcohols, C12-16, ethoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, alcohols, C12-16, ethoxylated do not meet the criteria for toxicity.

The overall conclusion is that alcohols, C12-16, ethoxylated is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]
Eye Irritant Category 2
Skin Irritant
Aquatic Chronic Toxicity Category 3

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions
Prevent from entering sewers, waterways, or low area

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for alcohols, C12-16, ethoxylated.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Wear respiratory protection if ventilation is inadequate.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Chemical safety goggles.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Alcohols, C12-16, ethoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ALDOL
[3-HYDROXYBUTANAL]

This dossier on aldol presents the most critical studies pertinent to the risk assessment of aldol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 3-Hydroxybutanal

CAS RN: 107-89-1

Molecular formula: $C_4H_8O_2$

Molecular weight: 88.11

Synonyms: Aldol; 3-hydroxybutanal; butanal, 3-hydroxy-; 3-hydroxybutyraldehyde; oxybutanal; acetaldol

SMILES: CC(CC=O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Aldol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless, thick liquid	4	HSDB, 2019
Melting point	>83°C (decomposes)	4	HSDB, 2019
Density	1.103 g/cm^3 @ 20°C	4	HSDB, 2019
Vapor pressure	175 Pa @ 25°C (QSAR)	2	EPA, 2019
Partition coefficient (log K_{ow})	-0.722 (QSAR)	2	EPA, 2019
Water solubility	Miscible	4	HSDB, 2019
Flash point	66°C	4	HSDB, 2019
Auto flammability	250°C	4	NFPA, 2010

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is not expected to accumulate in the environment and is predicted to readily degrade.

B. Biodegradation

No experimental data are available. Using BIOWIN v. 4.10, aldol is predicted to be readily biodegradable (EPA, 2019).

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for aldol. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} is 0.77 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.0 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on aldol. Aldol is not expected to bioaccumulate based on a log K_{ow} of -0.722 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Limited data are available to assess the hazards associated with this substance. However, classification information obtained from credible agency sources suggests the substance is toxic via oral, dermal and inhalation exposure routes.

B. Acute Toxicity

An LD50 Oral for rat has been listed as 2,180 mg/kg while the LD50 Dermal in the rabbit is given as 140 mg/kg (Millipore 2020).

No data are available for inhalation exposures.

C. Irritation

No studies are available.

D. Sensitization

No studies are available.

E. Repeated Dose Toxicity

No studies are available.

F. Genotoxicity

No studies are available.

G. Carcinogenicity

No studies are available. Further, no component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC, ACGIH, NTP, or OSHA (Millipore 2020).

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

No studies are available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No studies are available on aldol. Toxicological reference and drinking water guidance values were not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Aldol does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

No acute or chronic aquatic studies were available. Estimates of acute toxicity were made using EPISUITE and indicate a relatively low order of aquatic toxicity.

B. Aquatic Toxicity

Acute Studies

There are no experimental acute aquatic toxicity data on aldol. Table 2 lists the estimated acute aquatic toxicity values on aldol using ECOSAR v.1.11 (EPA, 2019).

Table 2: Acute Aquatic Toxicity Studies on Aldol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Fish	96-hr LC_{50}	134	2	EPA, 2019
Daphnid	48-hr EC_{50}	840	2	EPA, 2019
Green Algae	96-hr EC_{50}	692	2	EPA, 2019

Chronic Studies

No experimental studies are available.

C. Terrestrial Toxicity

No experimental studies are available.

D. Calculation of PNEC

The PNEC calculations for aldol follow the methodology discussed in DEWHA (2009).

PNEC water

Estimated results using ECOSAR are available for three trophic levels. Acute $E(L)C_{50}$ values are for fish (134 mg/L), invertebrates (840 mg/L), algae (692 mg/L). On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported $E(L)C_{50}$ value of 134 mg/L for fish. The $PNEC_{water}$ is 0.13 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.002 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

$= (0.02/1500) \times 1000 \times 0.13$

$= 0.002$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
= 1.0 x 0.02
= 0.02

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for aldol based on the molecular connectivity index (MCI) is 1.0 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Aldol is expected to be readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -0.722, aldol does not meet the screening criteria for bioaccumulation.

There are no experimental aquatic toxicity data on aldol. The predicted acute $E(L)C_{50}$ values are >1 mg/L for fish, invertebrates, and algae. Thus, aldol does not meet the screening criteria for toxicity.

Therefore, aldol is not considered a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Tox. 2	H310
Eye Irrit. 2	H319
Acute Tox. 2	H310
Eye Irrit. 2	H319

B. Labelling

According to the classification provided by companies to ECHA in CLP notifications this substance is fatal in contact with skin and causes serious eye irritation.

Danger Acute toxicity [dermal H310 (100%)]
Causes serious eye irritation [Warning Serious eye damage/eye irritation] H319 (100%)

Precautionary statement(s)
P262 Do not get in eyes, on skin, or on clothing.

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ eye protection/ face protection.
P302 + P350 IF ON SKIN: Gently wash with plenty of soap and water.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P361 Remove/Take off immediately all contaminated clothing.
P363 Wash contaminated clothing before reuse.
P405 Store locked up.

P501 Dispose of contents/ container to an approved waste disposal plant.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

The following information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of knowledge and is applicable to the product with regard to appropriate safety precautions.

A. First Aid

Eye Contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact
Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

Inhalation
If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion
Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

Notes to Physician
Basic Treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Aggressive airway management may be necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Anticipate seizures and treat if necessary. Monitor for shock and treat if necessary. Monitor for pulmonary edema and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex, and does not drool. Administer activated charcoal (Currance et.al. 2007).

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary edema, or is in respiratory distress. Intubation should be considered at the first sign of upper airway obstruction caused by edema. Positive-pressure ventilation techniques with a bag-valve-mask device may be beneficial. Consider drug therapy for pulmonary edema. Considering administering a beta agonist such as albuterol for severe bronchospasm. Start IV administration of D5W TKO /SRP: "To keep open", minimal flow rate. Use 0.9% saline (NS) or lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload. Treat seizures with diazepam (Valium) or lorazepam (Ativan) ... Use proparacaine hydrochloride to assist eye irrigation. (Currance et.al. 2007)

Medical Conditions Aggravated by Exposure
None listed

Emergency Personnel Protection
See Section E

B. Fire Fighting Information

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Specific Exposure Hazards
Carbon oxides may be generated.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus for firefighting if necessary.

C. Accidental Release Measures

Personal Precautions
Avoid contact with skin or exposed areas of the body. Avoid inhalation of vapor or fumes.

Environmental Precautions
Prevent release to drains and surface water.

Steps to be Taken if Material is Released or Spilled
Follow local recommended pollution prevention procedures to prevent environmental release.

D. Storage And Handling

General Handling
Avoid contact with skin and eyes. Avoid inhalation of vapour or mist.
Normal measures for preventive fire protection.

Other Handling Precautions
None

Storage
Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage.
Storage class (TRGS 510): 6.1B: Non-combustible, acute toxic Cat. 1 and 2 / very toxic hazardous materials

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for aldol.

Engineering Controls
Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal Protection Equipment
Respiratory Protection:
Where risk assessment shows air-purifying respirators are appropriate use a fullface respirator with multi-purpose combination (US) or type ABEK (EN 14387)
respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand Protection:
Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Skin Protection:
Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Eye protection:
Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Other Precautions:
Prevent further leakage or spillage if safe to do so. Do not let product enter drains Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal.

F. Transport Information

DOT (US) UN number: 2839 Class: 6.1 Packing group: II
Proper shipping name: Aldol Poison Inhalation Hazard:
No IMDG
EMS-No: F-A, S-A Proper shipping name: ALDOL IATA UN number: 2839 Class: 6.1 Packing group: II Proper shipping name: Aldol

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Currance, P.L. Clements, B., Bronstein, A.C. (Eds).; Emergency Care For Hazardous Materials Exposure. 3rd revised edition, Elsevier Mosby, St. Louis, MO 2007, p. 266

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HSDB (2019). Hazardous Substances Data Bank (HSDB), U.S. National Library of Medicine. Accessed on 26 May, 2019. https://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Millipore 2020. Millipore Sigma SDS for Aldol. Version 6.1 Revision Date 01/13/2020 Print Date 02/04/2020 (https://www.sigmaaldrich.com/MSDS/MSDS/DisplayMSDSPage.do?country=US&language=en&productNumber=S426822&brand=ALDRICH&PageToGoToURL=https%3A%2F%2Fwww.sigmaaldrich.com%2Fcatalog%2Fsearch%3Fterm%3Daldol%26interface%3DAll%26N%3D0%26mode%3Dmatch%2520partialmax%26lang%3Den%26region%3DUS%26focus%3Dproduct

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

AMIDES, TALL OILS FATTY, N,N-BIS(HYDROXYETHYL)

This dossier on amides, tall oils fatty, N,N-bis(hydroxyethyl) presents the most critical studies pertinent to the risk assessment of amides, tall oils fatty, N,N-bis(hydroxyethyl) in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997; Kl).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Amides, tall oils fatty, N,N-bis(hydroxyethyl)

CAS RN: 68155-20-4

Synonyms:

Synonyms for oleamide DEA listed below.

While no specific composition data are available on amides, tall oils fatty, N,N-bis(hydroxyethyl), it is expected to be a mixture of diethanolamides of the fatty acids that constitute tall oil, which is composed of predominantly C18 unsaturated fatty acids: 48% oleic acid, 35% linoleic acid, 7% conjugated linoleic acid (REF).

As there are no available studies on CAS 68155-20-4, this dossier is based on information on Amides, C18-unsatd, N,N-bis(hydroxyethyl) [CAS No. 93-83-4]. This is justified because amides, tall oils fatty, N,N-bis(hydroxyethyl) is predominantly diethanolamides of unsaturated C18 fatty acids similar to the composition of the target substance CAS 68155-20-4.

AMIDES, C18-UNSATURATED, N,N-BIS(HYDROXYETHYL)

Chemical Name: Oleamide DEA

CAS RN: 93-83-4

Molecular formula: $C_{22}H_{43}NO_3$ (UVCB substance)

Molecular weight: 369.6 g/mol (UVCB substance)

Synonyms for oleamide DEA:
Oleyl diethanolamide;(9Z)-N,N-Bis(2-hydroxyethyl)-9-octadecenamide; (z)-n,n-bis(2-hydroxyethyl)-9-octadecenamide; 9-Octadecenamide, N,N-bis(2-hydroxyethyl)-, (Z)-; Alkamide DO-280;
N,N-Bis(2-hydroxyethyl)-9-octadecenamide; Alrosol O; Amisol ode; Clindrol 2000; Clindrol 2020, Comperlan OD; Diethanololeamide; EMID 6545; Emulsifier WHC; Lauridit OD; Mackamide O, Marlamid D 1885, N,N-Diethanololeamide, Nitrene NO, Oleamide, N,N-bis(2-hydroxyethyl)-, Oleic acid diethanolamide, Oleic acid diethanolamine condensate, Oleic diethanolamide, Schercomid ODA, Stafoam DO, Steinamid DO 280SE, Witcamide 511C

SMILES: CCCCCCCC\C=C/CCCCCCCC(=O)N(CCO)CCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Amides, C18-unsatd, N,N-bis(hydroxyethyl) [CAS No. 93-83-4]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid	2	ECHA
Melting point	ca. -80°C	1	ECHA
Boiling point	>300°C	1	ECHA
Density	0.967 g/cm^3@ 20°C	1	ECHA
Vapor pressure	0 Pa @ 25°C	1	ECHA
Partition coefficient (log K_{ow})	>6 (experimental)	1	ECHA
Water solubility	<1 mg/L @ 20°C	1	ECHA
Flash point	218°C	1	ECHA
Auto flammability	350°C	1	ECHA
Viscosity	805.87 mPa s @ 20°C	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

According to ECHA, hydrolysis studies were not conducted; “the study does not need to be conducted because the substance is readily biodegradable.” (ECHA)

B. Biodegradation

Amides, C18-unsatd, N,N-bis(hydroxyethyl) is readily biodegradable. In an OECD 301 D test, degradation was 70% after 28 days (ECHA) [Kl. score = 1]. In an OECD 301 B test, degradation was 79% after 14 days and 86% after 28 days (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for amides, C18-unsatd, N,N-bis(hydroxyethyl). Using KOCWIN v2.00, the estimated K_{oc} values for the individual components were calculated using the molecular connectivity index (MCI) approach. The final K_{oc} value was calculated on a weighted-average basis using the mole fractions of the individual components. The final K_{oc} value is 1,717 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on amides, C18-unsatd, N,N-bis(hydroxyethyl). The bioaccumulation potential of amides, C18-unsatd, N,N-bis(hydroxyethyl) was estimated using BCFBAF v3.01. The final BCF was calculated on a weighted-average basis using the mole fractions of all individual components. The calculated BCF was 112.53 L/kg, indicating a low potential for bioaccumulation (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

Human health toxicity data were obtained from ECHA, unless another source is explicitly cited.

A. Summary

Amides, C18-unsatd, N,N-bis(hydroxyethyl) are considered acutely toxic and an skin and eye irritant. It is not considered a skin sensitizer or toxic via repeated doses, and has no reported reproductive or developmental effects. It is not considered genotoxic or carcinogenic.

B. Acute Toxicity

Amides, C18-unsatd, N,N-bis(hydroxyethyl) is considered acutely toxic via oral route of exposure, with an LD50 of 10,000 mg/kg in male Sprague-Dawley rats (Kl = 2).

C. Irritation

Based on the available data, the test substance is considered irritating to both the skin and eyes. The available in vivo studies demonstrate:

- Clear irritation response following semi-occlusive exposure to the test substance for 24 h. The data support a classification as Skin Irrit. 2 - H315 (causes skin irritation) according to CLP (EC 1272/2008) criteria (Kl =1).
- Undiluted test substance showed irritation to rabbit eyes and supports classification as Eye Irrit. 2 – H319 (causes serious eye irritation) according to CLP (EC 1272/2008) criteria (Kl = 1).

D. Sensitization

The test substance is not expected to be a skin sensitiser based on a negative in vivo skin sensitisation study conducted on a structurally similar substance (Kl=1). Therefore no classification is required for sensitisation according to CLP (EC 1272/2008) criteria. There are no data on the respiratory sensitization potential of the substance.

E. Repeated Dose Toxicity

Based on the NOAEL derived from an oral subacute study in rat (>750 mg/kg bw/day) in which no treatment-related effects were observed, and observed effects in a chronic dermal study in rat (NOAEL of 50 mg/kg bw/day for systemic effects and LOAEL of 50 mg/kg bw/day for local effects), the test substance is not considered to meet the requirements for repeated dose toxicity classification according to CLP (EC 1272/2008) criteria. There are no data to evaluate the repeated dose toxicity classification for the inhalation exposure route.

F. Genotoxicity

The test substance and read across substance (amides, C8-18 (even numbered) and C18-unsatd. N,N bis(hydroxyethyl) were negative in short-term in vitro and in vivo genotoxicity tests. Therefore no classification is required for this endpoint according to CLP (EC 1272/2008) criteria.

In Vitro Studies
The *in vitro* studies conducted for this substance are described in Table 2. The referenced studies indicate that the substance is not mutagenic or genotoxic *in vitro*.

Table 2: *In vitro* Genotoxicity Studies

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
In vitro gene mutation study in bacteria (*S. typhimurium* TA97, TA98, TA100 and TA1535)	-	-	2	Irwin, 1999**
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	Irwin, 1999**
Bacterial reverse mutation (S. typhimurium and E. coli strains)	-	-	1	Verspeek-Rip, 2014**

*+, positive; -, negative. ** As cited in ECHA.

In Vivo Studies

A study was conducted to evaluate the potential of the test material to induce micronuclei in B6C3F1 mice. Under the conditions of the study, the test substance did not increase the frequencies of micronucleated normochromatic erythrocytes (NCEs) in peripheral blood of both male and female mice at the end of 13 weeks (Kl =1).

G. Carcinogenicity

No studies are available for assessing the carcinogenicity of this substance via the oral or inhalation routes of exposure.

Rodent tests indicate that the substance is not carcinogenic by the dermal route. A study was conducted to evaluate the effects of chronic exposure to the test substance in B6C3F1 mice. Under the test conditions, no evidence of carcinogenic activity was observed with the test substance at any tested dose levels in mice (Kl =1). A study was conducted to evaluate the effects of chronic exposure to the test substance in F344/N rats. Under the test conditions, no evidence of carcinogenic activity was observed with the test substance at any tested dose levels in rats (Kl =1).

H. Reproductive and Developmental Toxicity

No studies were available to assess the effects of the substance on reproduction. No adverse developmental effects were observed following administration of 1,000 mg/kg bw day to pregnant Sprague-Dawley rats (Kl = 2).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is a 750 mg/kg bw/day based on bodyweight, hematology, clinical chemistry, urinalysis, gross and microscopic pathology in male and female rats from a 28-day oral gavage study (Potokar, 1983). The NOAEL of 750 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 750/(10 x 10 x 1 x 10 x 1) = 750/1000 = 7.5 mg/kg-day

Drinking water guidance value

The drinking water guidance value is calculated as:

(animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD, the drinking water guidance value is calculated as:

(oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)

Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (7.5 x 70 x 0.1)/2 = 26.3 mg/L

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on amides, C18-unsatd, N,N-bis(hydroxyethyl).

Table 3: Acute Aquatic Toxicity Studies on Amides, C18-unsatd, N,N-bis(hydroxyethyl)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-hr LC_{50}	5.1	1	ECHA
Daphnia magna	48-hr EC_{50}	3.2	2	ECHA
Desmodesmus subspicatus	72-hr EC_{50}	18.6	2	ECHA

Chronic Studies

The 28-day NOEC to *Oncorhynchus mykiss* in a fish chronic toxicity study is 0.32 mg/L [nominal] and 0.26 mg/L [measured] (ECHA) [Kl. score = 2].

The 21-d NOEC in a *Daphnia* reproduction test is 0.1 mg/L [nominal] and 0.07 mg/L [measured] (ECHA) [Kl. score = 2].

The 72-hr EC_{10} to *Desmodesmus subspicatus* is 1.4 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for amides, C18-unsatd, N,N-bis(hydroxyethyl) follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (5.1 mg/L), invertebrates (3.2 mg/L), and algae (18.6 mg/L). Results from chronic studies are available for fish (0.26 mg/L), invertebrates (0.07 mg/L), and algae (1.4 mg/L). On the basis that the data consists of short-term and long-term results for three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC or EC_{10} value of 0.07 mg/L for invertebrates. The $PNEC_{water}$ is 0.007 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.16 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (34.34/1500) \times 1000 \times 0.007$
$= 0.16$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1717 \times 0.02$
$= 34.34$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for Amides, C18-unsatd, N,N-bis(hydroxyethyl) based on the molecular connectivity index (MCI) is 1,717 L/kg (ECHA).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Amides, C18-unsatd, N,N-bis(hydroxyethyl) is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on an estimated BCF value of 113 L/kg, amides, C18-unsatd, N,N-bis(hydroxyethyl) does not meet the criteria for bioaccumulation.

The lowest chronic NOEC or EC_{10} value for amides, C18-unsatd, N,N-bis(hydroxyethyl) is <0.1 mg/L. Thus, amides, C18-unsatd, N,N-bis(hydroxyethyl) meets the criteria for toxicity.

The overall conclusion is that amides, C18-unsatd, N,N-bis(hydroxyethyl) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Skin Irritant Category 2
Eye Irritant Category 2
Aquatic Chronic Toxicity Category 2

May cause respiratory tract irritation.

B. Labelling

Danger.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse thoroughly for at least 15 minutes and consult a physician.

Skin Contact
Remove contaminated clothing. Wash with soap and plenty of water. Consult a physician immediately.

Inhalation
Move the person to fresh air.

Ingestion
Rinse mouth with water; consult a physician immediately. Do not induce vomiting.

Notes to Physician
No data available

Medical Conditions Aggravated by Exposure
No data available

Emergency Personnel Protection
No additional notes

B. Fire Fighting Information

Extinguishing Media
Water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

Specific Exposure Hazards
May be combustible at high temperatures; container explosion may occur under fire conditions or if heated. Hazardous combustion products include carbon oxides and nitrogen oxides.

Special Protective Equipment for Firefighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

C. Accidental Release Measures

Personal Precautions
Remove all sources of ignition. Ensure adequate ventilation. Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist, or gas. Evacuate unprotected persons.

Environmental Precautions
Stop the spill if possible and safe. Prevent from reaching drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilled
Contain spill material by diking or using inert absorbent such as vermiculite, dry sand, or earth. Transfer to a disposal or recovery container.

D. Storage And Handling

General Handling
Avoid contact with skin and eyes. Avoid formation of dust and aerosols.

Other Handling Precautions
Provide appropriate exhaust ventilation at places where dust is formed. Do not eat or drink while working with chemical substances.

Storage
Store in a cool, dry, well-ventilated place. Keep container tightly closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
No data available.

Engineering Controls
Provide ventilation.

Personal Protection Equipment

Respiratory Protection:
Wear dust mask when handling large quantities

Hand Protection:
Wear impervious gloves, inspect gloves before use.

Skin Protection:
Wear impervious clothing; PPE is to be selected according to the concentration and amount of the substance to be handled.

Eye protection:
Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Other Precautions:
No data available

F. Transport Information

UN Number: Not regulated

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS
AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

AMINE OXIDES, COCOALKYLDIMETHYL

This dossier on amine oxides, cocoalkyldimethyl presents the most critical studies pertinent to the risk assessment of amine oxides, cocoalkyldimethyl in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on amine oxides (OECD, 2006). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Amines, oxides, cocoalkyldimethyl

CAS RN: 61788-90-7

Molecular formula: Not available (UVCB substance)

Molecular weight: No available (UVCB substance)

Synonyms:

SMILES: Not available (UVCB substance)

The typical alkyl chain length distribution of amine oxides, cocoalkyldimethyl is: <1-3 C_{10}; 64-74 C_{12}; 21-30 C_{14}; 2-13 C_{16}; and <1-9 C_{10}. The average alkyl chain is 13.0 (OECD, 2006).

II. PHYSICAL AND CHEMICAL PROPERTIES

Specific physico-chemical properties on amine oxides, cocoalkyldimethyl are unavailable. Therefore, data from a similar substance, CAS No. 70592-80-2, are presented below.

Table 1: Overview of the Physico-chemical Properties of Amines, C10-16- Alkyldimethyl, N-oxides, Average Chain Length 12.6* [CAS No. 70592-80-2] (OECD, 2006)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid (commercially available in water at 25-35% activity)	-	OECD, 2006
Melting point	Average: 130.5°C	2	OECD, 2006
Boiling point	Decomposes before boiling***	2	OECD, 2006
Vapor pressure	Negligible	2	OECD, 2006
Partition coefficient (log K_{ow})	<2.7	2	OECD, 2006

Property	Value	Klimisch score	Reference
Water solubility	409.5	2	OECD, 2006

*Except melting point.
**Aliphatic amine oxides undergo thermal decomposition between 90° and 200°C. So, melting point is likely to be accompanied with decomposition; all boiling points are predicted to be far above the decomposition temperature.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is not expected to persist, adsorb, or bioaccumulate. Specific data are discussed below.

B. Biodegradation

Amine oxides, cocoalkyldimethyl is readily biodegradable. In an OECD 301 D test, degradation was 89% after 14 days and 93% after 28 days (OECD, 2006) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for amine oxides, cocoalkyldimethyl.

An adsorption-desorption study using a batch equilibrium method (OECD TG 106) was conducted on amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS No. 308062-28-4). Three soil types were used and two homologues (C_{12} and C_{14}) of the test material were evaluated (ECHA) [Kl. score = 1].

In the ECHA database for amines, C12-16 (even numbered)-alkyldimethyl,N-oxides (CAS No. 85408-49-7), a K_{oc} value of 1,525 L/kg was calculated from the adsorption-desorption study on C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS No. 308062-28-4) (ECHA).

The K_{oc} value of 1,525 L/kg will be used for amine oxides, cocoalkylmethyl based on read-across from amines, C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS No. 308062-28-4). C12 and C14 are the major alkyl carbon lengths for amine oxides, cocoalkylmethyl.

D. Bioaccumulation

There are no bioaccumulation studies on amine oxides, cocoalkyldimethyl. Amine oxides, cocoalkyldimethyl is not expected to bioaccumulate based on a log K_{ow} of <2.7 (OECD, 2006).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Data discussed below are taken from OECD (2006). In general, the substance does not exhibit significant acute oral or dermal toxicity. It appears to illicit irritation reactions in lab animals. It not a sensitizer, a reproductive toxicant, genotoxic or expected to be a carcinogen or developmental toxicant.

B. Toxicokinetics/Metabolism

Following an oral dose to male and female rats, approximately 75% of the radioactivity was excreted within 24 hours. Excretion was primarily in the urine (>50%), followed by feces and expired CO_2. The amount of test compound recovered in liver was 1.1 to 1.5%; 1.9 to 4.8% of the dose was retained in the carcass, with the remaining tissues $\leq$0.1% of the dose. Degradation of the alkyl chain to 4-carbon acid metabolites was more efficient in rabbits (OECD, 2006).

In two human volunteers, the uptake and excretion of 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) was rapid, with 37 to 50% of the administered radioactivity collected in urine and 18 to 22% in the expired air within two hours after dosing. Humans were more efficient than rats in metabolizing the alkyl chain to 4-carbon acid metabolites (Turan and Gibson, 1981).

C. Acute Toxicity

The oral LD_{50} in rats of amine oxides, cocoalkyldimethyl was 1,236 mg/kg in males and 846 in females (OECD, 2006) [Kl. score = 2]. In another study, the oral LD_{50} in rats of amine oxides, cocoalkyldimethyl was 3,873 mg/kg (OECD, 2006) [Kl. score = 2].

No inhalation studies available.

The dermal LD_{50} values of amines, C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) were >520 mg/kg (OECD, 2006) [Kl. score = 2].

D. Irritation

Application of amine oxides, cocoalkyldimethyl (30% solution) to the skin of rabbits for 4 hours under semi-occlusive conditions was irritating (OECD, 2006 [Kl. score = 1].

Instillation of a 30% solution of 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) into the eyes of rabbits was slightly irritating (OECD, 2006) [Kl. score = 2].

Instillation of 28% solution of C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) into the eyes of rabbits was moderately to severely irritating (OECD, 2006) [Kl. score = 2]. In another study, Instillation of 27.84% solution of C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) into the eyes of rabbits was moderately irritating (OECD, 2006) [Kl. score = 2].

E. Sensitization

No studies are available on amine oxides, cocoalkyldimethyl.

C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) was not considered to be a skin sensitizer in a guinea pig Buehler test (OECD, 2006) [Kl. score = 2].

F. Repeated Dose Toxicity

No studies are available on amine oxides, cocoalkyldimethyl.

Oral
Male and female SD rats were given in their diet 0, 0.1, 0.2, or 0.4% C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) for 13 weeks. The estimated daily intakes were: 0, 63, 112, and 236 mg/kg-day for males; and 0, 80, 150, and 301 mg/kg-day for females. Mean body weights were significantly lower in the 0.4% males and ≥0.2% females. The opthalmoscopic examination showed lenticular opacities in the posterior cortex of the ≥0.2% males. There were no treatment-related effects in the clinical chemistry and hematology parameters; nor was there any histopathologic changes in the treated animals compared to controls. The NOAEL for this study is 0.1% in the diet, which corresponds to 63 and 80 mg/kg-day for males and females, respectively (OECD, 2006) [Kl. score = 2].

Male and female New Zealand rabbits were given in their diet 0, 0.1, 0.5, or 1.0% C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) for 32 weeks. The estimated daily intakes were: 0, 40, 196, and 390 mg/kg-day for males; and 0, 39, 195, and 380 mg/kg-day for females. There were no opthalmoscopic effects. The 0.5% males had decreased alkaline phosphatase levels and increased relative liver weights. Histopathologic examination showed no treatment-related effects. The NOAEL for this study is 1% in the diet, which corresponds to 390 and 380 mg/kg-day for males and females, respectively (OECD, 2006) [Kl. score = 2].

Male and female rats were given in their diet 0, 0.1, 0.1, or 0.2% C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) for 104 weeks. The estimated daily intakes were: 0, 4.24, 42.3, or 87.4 mg/kg-day for males; and 0, 5.23, 52.6, or 107 mg/kg-day for females. Survival, clinical chemistry, opthalmoscopic exams, clinical signs, gross pathology, and histopathology were similar across groups. The 0.2% animals had reduced body weights of >10%. The NOAEL for this study is 0.1% in the diet, which corresponds to 42 and 53 mg/kg-day for males and females, respectively (OECD, 2006) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
Male and female ICR Swiss mice received dermal applications of an aqueous solution of C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) 3 times/week for 104 weeks. The average daily dose was 0, 1.1, 2.8, or 5.6 mg/kg-day. The high-dose mice showed microscopic signs of skin irritation. There were no other treatment-related effects (OECD, 2006) [Kl. score = 2].

G. Genotoxicity

In Vitro Studies

The in vitro genotoxicity studies on amine oxides, cocoalkyldimethyl and similar substances are shown in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Amine Oxides, Cocoalkyldimethyl

Test System	Results**		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (Chinese hamster fibroblasts)**	-	-	1	ECHA

*+, positive; -, negative
**Read-across from C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2).

In Vivo Studies

In a dominant lethal test, male mice were given in their drinking water 0, 10, 100, or 1,000 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5). There was no evidence of a mutagenic effect (OECD, 2006) [Kl. score = 2].

H. Carcinogenicity

No carcinogenicity studies are available on amine oxides, cocoalkyldimethyl.

Oral
Male and female rats were given in their diet 0, 0.1, 0.1, or 0.2% C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) for 104 weeks. The estimated daily intakes were: 0, 4.24, 42.3, or 87.4 mg/kg-day for males; and 0, 5.23, 52.6, or 107 mg/kg-day for females. The incidence of tumors was similar between treated and control animals (OECD, 2006) [Kl. score = 1].

Dermal
Male and female ICR Swiss mice received dermal applications of an aqueous solution of C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) 3 times/week for 104 weeks. The average daily dose was 0, 1.1, 2.8, or 5.6 mg/kg-day. The high-dose mice showed microscopic signs of skin irritation. There was no evidence of skin tumors at any dose level (OECD, 2006) [Kl. score = 2].

I. Reproductive Toxicity

A two-generation reproductive toxicity study has been conducted in CD rats on 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5). The dietary levels were 0, 750, 1,500, and 3,000 ppm for 6.5 weeks, and 0, 188, 375, and 750 ppm for the remainder of the

study. The dietary levels were reduced because of the reduced body weight gain in the mid- and high-dose groups. There were slight reductions in body weight gain of both the parental animals and offspring, but mating performance and fertility were unaffected by treatment in either generation. Macroscopic and microscopic pathologic examinations showed no differences between treated and control groups. The NOAEL for reproductive and developmental toxicity is 750 ppm, which corresponded to 40 mg/kg-day (OECD, 2006) [Kl. score = 1].

J. Developmental Toxicity

Pregnant female CD rats were dosed by oral gavage with 0, 50, 100, or 200 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) on GD 7 to 17. One-half of the females/group were sacrificed on GD 20, and the other half were allowed to deliver; the pups were weaned at PND 25 and the F_1 animals were paired at 10 weeks of age. Body weights and water consumption were lower (<10%) in the 200 mg/kg group. Mean fetal weights were lower and associated with slight retardation of fetal ossification in the 200 mg/kg group that were sacrificed in GD 20. However, pup survival and pup growth were unaffected in the offspring of the 200 mg/kg group that were allowed to deliver. The subsequent growth, mating performance, and fertility of the F_1 animals were similar between treated and control groups; F_1 females from the 200 mg/kg F_0 group had slightly elevated fetal and placental weights. There were no macroscopic changes seen in the F_1 animals at terminal necropsy that were considered to be treatment-related. The NOAEL for maternal and developmental toxicity is 100 mg/kg-day (OECD, 2006) [Kl. score = 1] suggesting that observations of developmental toxicity are related to maternal effects

Pregnant female SD rats were dosed by oral gavage with 0, 25, 100, or 200 mg/kg C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) on GD 6-19. There was one death in the 200 mg/kg group. The $\geq$100 mg/kg groups had reduced body weight gain and relative feed consumption. In the 200 mg/kg group, early resorptions were increased, and liver litter sizes and fetal body weights were decreased. The reduced fetal body weights were associated with fetal variations consisting of delays in skeletal ossifications. The 100 mg/kg group also showed some delays in ossification. There was no indication of fetal malformations at any dose level. The NOAEL for maternal and developmental toxicity is 25 mg/kg-day (OECD, 2006) [Kl. score = 2]. suggesting that observations of developmental toxicity are related to maternal effects.

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 40, 80, or 160 mg/kg 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) on GD 6-18. Three of the 80 mg/kg and three of the 160 mg/kg dams died or were killed in extremis; these deaths were not considered to be treatment-related. Body weight gain was reduced in all treated groups, although 40 mg/kg dams achieved similar body weights to controls at study termination. Feed consumption was reduced compared to the pre-treatment period during the second half of the treatment period in the 40 and 80 mg/kg animals and for the entire treatment period in the 160 mg/kg animals. Water consumption was also decreased in all treated groups. There was no indication of developmental toxicity. The NOAEL for maternal toxicity was considered to be 160 mg/kg-day because body weight gain, feed and water consumption did not exceed 10%. The NOAEL for developmental toxicity is 160 mg/kg-day, the highest dose tested (OECD< 2006) [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for amine oxides, cocoalkyldimethyl follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

In a long term two-year rat dietary study, the lowest NOAEL was 42 mg/kg-day (OECD, 2006). The NOAEL of 42 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 42/(10 x 10 x 1 x 1 x 1) = 42/100 = 0.4 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.42 x 70 x 0.1)/2 = 1.5 mg/L

B. Cancer

There are no carcinogenicity studies on amine oxides, cocoalkyldimethyl. However, C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) was not carcinogenic to rats in a 2-yr dietary

study; nor was there any evidence of skin tumors in mice in a 104-week dermal study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Amine oxides, cocoalkyldimethyl does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute and chronic aquatic toxicity studies were performed on a variety of species/trophic levels with algae exhibiting greater sensitivity to the substance. Study results are presented below.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on amine oxides, cocoalkyldimethyl.

Table 3: Acute Aquatic Toxicity Studies on Amine Oxides, Cocoalkyldimethyl

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Salmo gairdneri	96-hr LC_{50}	13	1	OECD, 2006
Brachydanio rerio	96-hr LC_{50}	1.0	2	OECD, 2006
Leuciscus idus melanotus	96-hr LC_{50}	4.3	2	OECD, 2006
Daphnia magna	48-hr EC_{50}	2.9	1	OECD, 2006
Selenastrum capricornutum	72-hr EC_{50}	0.29	2	OECD, 2006

Chronic Studies
The 302-d NOEC for C10-16 alkyldimethyl, N-oxides (CAS No. 70592-80-2) to *Pimephales promelas* was 0.42 mg/L; this value is 0.31 mg/L when normalized to a $C_{12.9}$ amine oxide (OECD, 2006) [Kl. score = 2].

The 21-day NOEC for 1-dodecanamine, N,N-dimethyl-, N-oxide (CAS No. 1643-20-5) in a *Daphnia* reproduction test is 0.36 mg/L; this value is 0.28 mg/L when normalized to a $C_{12.9}$ amine oxide (OECD, 2006) [Kl. score = 1].

The 72-hr NOEC for amine oxides, cocoalkyldimethyl to *Selenastrum capricornutum* is 0.09 mg/L (OECD, 2006) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for amine oxides, cocoalkyldimethyl follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (1.0 mg/L), invertebrates (2.9 mg/L), and algae (0.29 mg/L). Results from chronic studies are available for fish (0.31 mg/L), invertebrates (0.28 mg/L), and algae (0.09 mg/L). On the basis that the data consists of short-term and long-term studies for three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC value of 0.09 mg/L for algae. The $PNEC_{water}$ is 0.009 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.18 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (30.5/1500) \times 1000 \times 0.009$
$= 0.18$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1525 \times 0.02$
$= 30.5$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for amine oxides, cocoalkylmethyl is 1525 L/kg based on read-across from C12-14 (even numbered)-alkyldimethyl, N-oxides (CAS No. 308062-28-4) (ECHA) where, F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Amine oxides, cocoalkyldimethyl is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a predicted log K_{ow} of <2.7, amine oxides, cocoalkyldimethyl does not meet the screening criteria for bioaccumulation.

The lowest NOEC from chronic aquatic toxicity studies conducted on amine oxides, cocoalkyldimethyl and similar substances is <0.1 mg/L. The E(L)C_{50} values for fish and algae are ≤1 mg/L. Thus, amino oxides, cocoalkyldimethyl meets the screening criteria for toxicity.

The overall conclusion is that amine oxides, cocoalkyldimethyl is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Skin Irritant Category 2
Eye Damage Category 1
Aquatic Acute Category 1
Aquatic Chronic Category 2

B. Labelling

Danger!

According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life, causes serious eye damage, is harmful if swallowed and causes skin irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact with eyes, rinse immediately with plenty of water

Seek medical advice.
Call a physician immediately

Skin Contact
After contact with skin, wash immediately with plenty of soap and water.
Consult a physician.

Inhalation
Remove to fresh air. If breathing is irregular or stopped, administer artificial respiration.

Ingestion
Call a physician immediately.
Clean mouth with water and drink afterwards plenty of water.
Do not induce vomiting without medical advice.
Never give anything by mouth to an unconscious person.

Medical Conditions Aggravated by Exposure
Exposure to substance may aggravate individuals with asthma or other respiratory conditions.

Emergency Personnel Protection
CAUTION!
Wear appropriate protective equipment and respiratory protection where dusts or airborne particulates of unknown concentrations may be generated.

LARGE SPILLS: Self-contained breathing apparatus preferred

B. Fire Fighting Information

Extinguishing Media
Dry powder, Water spray, Foam

Specific Exposure Hazards
Heating or fire can release toxic gas.

Special Protective Equipment for Firefighters
In the event of fire, wear self-contained breathing apparatus

C. Accidental Release Measures

Personal Precautions
CAUTION!
Wear appropriate protective equipment and respiratory protection where dusts or airborne particulates of unknown concentrations may be generated. For large spills, self-contained breathing apparatus preferred.

Environmental Precautions
Do not release to drains or flush into surface water or sanitary sewer system.

Steps to be Taken if Material is Released or Spilled
Carefully shovel spills into appropriate containers for disposal.
Avoid generating dust. Wet residue with water and absorb with inert material (sand, earth, etc.) Transfer into appropriate containers for recovery or disposal. Keep spill out of sewers and open bodies of water.

D. Storage and Handling

General Handling
Provide sufficient air exchange and/or exhaust in work rooms. Avoid contact with skin and eyes.

Other Handling Precautions
Take precautionary measures against static discharges.

Storage
STORAGE: Keep container tightly closed.
To maintain product quality, do not store in heat or direct sunlight.
Keep in a dry, cool and well-ventilated place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for amine oxides, cocoalkyldimethyl.

Engineering Controls
Ensure adequate ventilation, especially in confined areas. Use explosion-proof electrical/ventilating/lighting/equipment. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protection Equipment
Respiratory Protection:
In the case of vapor formation use a respirator with an approved filter
Hand Protection:
Suitable material: Nitrile rubber
Skin Protection:
Choose protection according to amount/concentration of dangerous substance
No special protective equipment required.
Eye protection*:*
Tightly fitting safety goggles
Other Precautions:
Avoid contact with skin, eyes and clothing.
Wash hands before breaks and immediately after handling the product.

F. Transport Information

Australian Transportation Codes

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ACME Hardesty (2013). Material Safety Data Sheet for LAURYL AMINE OXIDE. CAS 61788-90-7 /1643-20-5 30% in water.

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2006). OECD-SIDS Initial Assessment Report and Dossiers for Amine Oxides. Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=B927B43D-8E91-4ADA-80E3-720D634E01C0.

Turan, T.S., and Gibson, W.B. (1981). A comparison of the elimination and biotransformation of dodecyldimethylamine oxide (DDAO) by rats, rabbits and man. Xenobiotica 11: 447-468.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

BENZALDEHYDE

This dossier on benzaldehyde presents the most critical studies pertinent to the risk assessment of benzaldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997; Kl).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Benzaldehyde

CAS RN: 100-52-7

Molecular formula: C7H6O

Molecular weight: 106.12

Synonyms:
Artificial Almond Oil;Benzaldehyde FFC; Benzenecarbonal; Benzenecarboxaldehyde;Benzoic aldehyde; Phenylmethanal; Almond artificial essential oil; Phenylmethanal benzenecarboxaldehyde; NCI-C56133; Oil of Bitter Almond;Artificial essential oil of almond; Benzene carbaldehyde;NA 1989; Artificial essential oil of almond; Artificial bitter almond oil; Benzene methylal; Benzoyl hydride; Ethereal oil of bitter almonds; Benzyaldehyde

SMILES: c1(C=O)ccccc1

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Benzaldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid, becoming yellowish on keeping; almond odor	2	ECHA
Melting point	-26°C	2	ECHA
Boiling point	179°C	2	ECHA
Density	1.042 @ 25°C	2	ECHA

Property	Value	Klimisch score	Reference
Vapor pressure	169 Pa @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	1.4 @ 25°C	1	ECHA
Water solubility	6.95 g/L @ 25°C	2	ECHA
Flash point	63°C	2	ECHA
Auto flammability	192°C	2	ECHA
Viscosity	1.321 mPa s @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Benzaldehyde is readily biodegradable. It is not expected to bioaccumulate. Experimental data for adsorption/ desorption are not available; the estimated K_{oc} value is 11.09 L/kg.

B. Biodegradation

Benzaldehyde is readily biodegradable. In an activate sludge test, degradation was approximately 100% after 19 days as measured by DOC removal (ECHA) [Kl. score = 2].

In a BOD test, degradation was >60% after 28 days as measured by O_2 consumption (ECHA) [Kl. score = 2].

In a CO_2 evolution test, degradation was about 60% in 7 days and 100% in 28 days (ECHA) [Kl. score = 2].

C. Environmental Distribution

<u>Adsorption/desorption</u>
No experimental data are available for benzaldehyde. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} is 32.69 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 11.09 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on benzaldehyde. Benzaldehyde is not expected to bioaccumulate based on a log K_{ow} of 1.4 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Benzaldehyde is hazardous and considered harmful if swallowed, with low dermal toxicity and no evidence of being a skin irritant. It has been reported to cause respiratory and eye irritation but is not currently classified as such. Although the chemical has produced skin sensitisation reactions in some tests, based on the weight of evidence, the chemical is not likely to be a skin sensitiser. Based on the data available, the chemical is not considered to cause serious damage to health from repeated oral exposure or through inhalation. No data are available to evaluate exposure vie the dermal pathway. The available information indicates that the chemical does not show specific reproductive or developmental toxicity. Overall, the data indicate that the chemical has no mutagenic or genotoxic potential. Although there is no mutagenic activity in bacterial systems, the chemical does have weak clastogenic effects in some mammalian cell assays. The available information indicates that the chemical does not show specific reproductive or developmental toxicity. The following sections detail the available and relevant literature on the toxicity of benzaldehyde. The information described below was obtained from NICNAS IMAP if available and the ECHA database. Please refer to those information sources for the studies referenced therein.

B. Acute Toxicity

The chemical is classified as hazardous with the risk phrase 'Harmful if swallowed' (Xn; R22) in HSIS (Safe Work Australia). The available animal and human data (see Acute toxicity: observation in humans) support this classification. Jenner et al., (1964; Kl = 2) tested effects of benzaldehyde on rats, guinea pigs and mice. Doses were administered by intubation. Animals died between 4 and 18h after dose administration, and an LD50 of 1,300 mg/kg bw was calculated.

Although limited information is available, the chemical is likely to have low acute dermal toxicity in animal tests following dermal exposure. In an acute dermal toxicity study in rabbits with limited available data, an LD50 of >1250 mg/kg bw was reported.

Although limited data are available, the available information indicates that the chemical has moderate acute toxicity in animal tests following inhalation exposure and is recommended for classification (refer to Recommendation section). An increased incidence of respiratory symptoms was noted among workers exposed to vapour of the chemical at atmospheric concentrations of >5 mg/m3 (see Acute toxicity: observation in humans).

C. Irritation

Although limited data are available, the available information indicates that the chemical is not likely to be a skin irritant but has been reported to be an eye irritant in animal studies. The available information is not sufficient to support a classification. In an inhalation toxicity study, human volunteers were exposed to 4.5 ppm (19.5 mg/m3) of the chemical for one minute. Irritation of the eyes and upper respiratory tract were observed. In an occupational study, workers exposed to the chemical vapour at atmospheric concentrations of >5 mg/m3 reported symptoms of slight eye irritation and considerable skin irritation.

D. Sensitisation

Although the chemical has produced skin sensitisation reactions in some tests, based on the weight of evidence, the chemical is not likely to be a skin sensitiser. It is also noted that the chemical is rapidly metabolised to benzoic acid in the skin. Clinical reports of allergy to the chemical are rare and benzoic acid has also been reported not to produce sensitisation in clinical trials in humans.

E. Repeated Dose Toxicity

Based on the data available, the chemical is not considered to cause serious damage to health from repeated oral exposure or through inhalation. Numerous studies on the repeated-dose toxicity of benzaldehyde are mentioned in the German MAK report on benzaldehyde (1998). In the following, only the most relevant studies for hazard assessment are presented.

<u>Inhalation</u>
In a short-term inhalation study, groups of 14 Sprague-Dawley rats per sex and group were exposed in whole animal exposure chambers on 14 consecutive days, for 6 hours a day, to benzaldehyde vapour in concentrations of 0, 500, 750 and 1000 mL/m3 (about 2200, 3300 and 4400 mg/m3). During the experiment 11 animals from the 1000 mL/m3 group died (10 females, 1 male) and 3 female animals from the 750 mL/m3 group. In all animals exposed to benzaldehyde, tremor, piloerection, diuresis, decreased respiration rates, hypothermia, reduced motor activity and concentration-dependent symptoms of eye and nose irritation occurred in the first week of the experiment. Because effects occurred even at the lowest benzaldehyde concentration of 500 mL/m3, this study did not yield a NOEL (Laham et al. 1991).

In albino rats exposed over a period of 4 months for 5 hours a day to benzaldehyde concentrations of 26 mglm3 (about 6.0 mL/m3) under dynamic conditions, 3 months after the beginning of the experiment changes were detected in haematological parameters (hypoglobulinaemia, erythrocytosis, leukocytosis, initial lymphocytosis

followed by lymphopenia) and delays in body weight gain. At the end of the experiment all the parameters were within the normal range.

Exposure to benzaldehyde concentrations of 6 mg/m3 (about 1.4 mL/m3) under otherwise identical conditions was tolerated by albino rats without symptoms (no further details) (Peresedov 1974).

Oral

Groups of 10 male and 10 female F344 rats were given gavage doses of benzaldehyde of 50, 100, 200, 400 and 800 mg/kg body weight (dissolved in corn oil) on 5 days/week for a period of 13 weeks. The symptoms of intoxication observed in the animals of the 800 mg/kg group were increased activity, trembling or periodic inactivity. 6 males and 3 females of this group and 1 female animal of the 400 mg/kg group and the control group died in the second half of the experiment. In the male animals of the 800 mg/kg group, body weight gains and the absolute and relative weights (relative to the brain weight) of the thymus and testes were reduced. The female animals of this group were found to have slightly increased liver, kidney, thymus and heart weights. In most of the animals of the 800 mg/kg group and 2 males of the 400 mg/kg group, slight hyperplasia and hyperkeratosis of the forestomach epithelium, accompanied by increased mitotic activity in the basement membrane, were detected. This study yielded a NOEL for of 400 mg/kg body weight per day as the damage to the forestomach is likely due to the application methodology (Kluwe et al. 1983, NTP 1990).

A study with the same design was also carried out with male and female B6C3F1 mice given benzaldehyde doses of 75, 150, 300, 600 or 1200 mg/kg body weight per day. No clinical symptoms of intoxication were observed. All male animals and one female from the 1200 mg/kg group died during the first 4 weeks of the experiment. The body weight gains were reduced in the female animals after doses of 1200 mg/kg and in the male animals after doses as low as 600 mg/kg. At the end of the experiment the body weights of the male animals of the 600 mg/kg group were reduced by 9 % relative to those of the controls. The organ weights did not differ from the control values. In the gross pathological and microscopic examinations, weak to moderate degeneration of the renal tubules was detected in all male animals of the 1200 mg/kg group and one male of the 600 mg/kg group. This study therefore yielded a NOEL for male mice of 300 mg/kg body weight per day and for female mice of 600 mg/kg body weight per day (Kluwe et al. 1983, NTP 1990).

F. Genotoxicity

Overall, the data indicate that the chemical has no mutagenic or genotoxic potential. Although there is no mutagenic activity in bacterial systems, the chemical does have weak clastogenic effects in some mammalian cell assays.

The genotoxicity of benzaldehyde has been investigated in many in vitro test systems. In Salmonella typhimurium, in mutagenicity studies with the strains TA98, TA100, TA102, TA104, TA1535, TA1537 and TA2637, and in a DNA repair lest with and without metabolic activation, no genotoxic activity could be detected. In a mutagenicity test with Escherichia coli WP2 uvrA and the mutagen 4-nitroquinoline-1-oxide, benzaldehyde from concentrations of 2120 µg/p1ate was found to have an antimutagenic effect (Watanabe et al. 1988). In Bacillus subtilis, DNA-damaging effects were observed at high concentrations only after metabolic activation. An increase in the incidence of mutants in the mouse lymphoma test occurred only in the high, cytotoxic concentration range and the finding is therefore questionable. Evidence of a weak clastogenic potential in the chromosomal aberration test and in the sister chromatid exchange test was also found only with high concentrations. Therefore, there is merely evidence of weak genotoxic activity of benzaldehyde.

In an *in* vivo test, a sex-linked recessive lethal test with *Drosophila melanogaster*, benzaldehyde administered in a concentration of 1500 ppm with the diet and injection of 2500 ppm was inactive (NTP 1990, Woodruff et al. 1985).

G. Carcinogenicity

Mammalian data are unclear on the carcinogenicity of benzaldehyde, showing some evidence of carcinogenicity in mice but none in rats. The chemical is also considered not to have mutagenic or genotoxic potential (see Genotoxicity).

In a carcinogenicity study, groups of 50 male and 50 female F344 rats and B6C3F1 mice were given gavage doses of benzaldehyde (dissolved in corn oil) on 5 days/week for a period of 103 to 104 weeks. The doses given to the female mice were 300 and 600 mg/kg body weight per day, and to all other groups 200 and 400 mg/kg body weight per day. Although tumors were found to form during the experiment, the increase in the incidence of some tumours in the male rats was not regarded as substance-related. An increase in the incidence of hyperplasia and squamous cell papillomas of the forestomach in mice were regarded as some evidence of carcinogenicity, but are probably the result of the irritative effects of benzaldehyde and are not of relevance because of the species-specific location.

Overall, therefore, there was no evidence in either mice or rats of a carcinogenic potential of benzaldehyde, which is in accordance with the, at most, low genotoxic activity of benzaldehyde in vitro.

H. Reproductive and Developmental Toxicity

Although limited data are available, the available information indicates that the chemical does not show specific reproductive or developmental toxicity. Benzyl derivatives, including benzaldehyde, have been reported to produce no evidence of

reproductive and developmental toxicity during various studies. It was also stated that as benzyl derivatives generally follow similar metabolic pathways, studies conducted on benzyl derivatives provide adequate evidence for benzaldehyde.

In one available study 10 female rats were given oral doses of 2 mg benzaldehyde per animal (about 5 mg/kg body weight and day) every second day for a period of 223 days, and were mated with untreated males on days 75 and 108 after the beginning of treatment. The number of offspring. the weight of the pups after 1 and 3 weeks and survival of the pups was in the range of the control values. The number of pregnant females in the lest group was decreased relative to that in the control group (Sporn et al. 1967). The study design (small number of treated animals, only one dose group) does not meet present-day standards and cannot, therefore, be regarded as evidence of impairment of female fertility. In a medium-term study with male F344 rats decreased testis weights were observed, but the effective dose of 800 mg/kg body weight (dissolved in corn oil, administered by gavage) was highly toxic and led to the death of 6 of 10 animals, so that this finding cannot be regarded as evidence of an impairment in fertility. In the 400 mg/kg group, in which there were no deaths or signs of intoxication, this effect did not occur (Kiuwe et al. 1983, NTP 1990).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for benzaldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is 400 mg/kg-day based on absence of effects in a 2-year gavage study in male and female rats. The NOAEL of 400 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 400/(10 x 10 x 1 x 1 x 1) = 400/100 = 4 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (4 x 70 x 0.1)/2 = 14 mg/L

B. Cancer

There was no evidence of carcinogenicity in rat and mouse chronic studies conducted on benzaldehyde. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Benzaldehyde does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary
A number of acute aquatic tests were available. In general, the acute tests indicate a relatively low order of toxicity for aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies conducted on benzaldehyde.

Table 2: Acute Aquatic Toxicity Studies on Benzaldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Fathead minnow	96-hr LC_{50}	12.4	2	ECHA
Rainbow trout	96-hr LC_{50}	11.2	2	ECHA
Goldfish	96-hr LC_{50}	13.8	2	ECHA
Channel catfish	96-hr LC_{50}	5.39	2	ECHA
Bluegill	96-hr LC_{50}	1.07	2	ECHA
Daphnia	24-hr EC_{50}	50	2	ECHA

Chronic Studies

In a juvenile growth test, the 7-day NOEC to 1- day *Pimephales promelas* larvae was 0.12 mg/L (measured) based on growth rate and mortality (ECHA) [Kl. score = 2].

The 8-day NOEC to *Scenedesmus quadricauda* is 34 mg/L (ECHA)
[Kl. score = 4].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for benzaldehyde follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (1.07 mg/L) and invertebrates (50 mg/L). Results from chronic studies are available for fish (0.12 mg/L) and algae (34 mg/L). On the basis that the data consists of short-term studies for two trophic levels and long-term results studies for two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC of 0.12 mg/L for fish. The $PNEC_{water}$ is 0.002 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.0003 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.22/1500) \times 1000 \times 0.002$
$= 0.0003$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 11.09 \times 0.02$
$= 0.22$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for benzaldehyde based on the molecular connectivity index (MCI) is 1.167 L/kg (EPA, 2018).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Benzaldehyde is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 1.4, benzaldehyde does not meet the screening criteria for bioaccumulation.

The lowest chronic NOEC for benzaldehyde is >0.1 mg/L. The acute $E(L)C_{50}$ values are >1 mg/L. Thus, benzaldehyde does not meet the screening criteria for toxicity.

The overall conclusion is that benzaldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable liquids Category 4
Acute toxicity – oral and dermal - Category 4
Eye irritant Category 2
Skin irritant Category 2

Respiratory sensitization Category 1
Skin sensitization Category 1
Acute aquatic toxicity Category 2

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

Skin Contact
Wash off with soap and plenty of water. consult a physician.

Inhalation
Move person to fresh air. If not breathing, give artificial respiration. Consult a physician.

Ingestion
Do NOT induce vomiting. Rinse mouth with water. Consult a physician.

Notes to Physician
Symptoms may occur even after several hours. Medical observation for at least 48 hours is recommended.

Benzaldehyde may cause allergy or asthma symptoms or breathing difficulties if inhaled.

Medical Conditions Aggravated by Exposure
No data available.

Emergency Personnel Protection
Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

B. Fire Fighting Information

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Specific Exposure Hazards
No data available.

Special Protective Equipment for Firefighters
No special measures required; Wear self-contained breathing apparatus for fire-fighting if necessary

C. Accidental Release Measures

Personal Precautions
Use personal protective equipment. Respiratory protection and/ or ventilation may be necessary to avoid breathing vapours, mist or gas. Remove all sources of ignition. Evacuate unprotected persons. Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

Environmental Precautions
Do not allow to enter sewers, drains, or waterways. Discharge into the environmental must be avoided.

Steps to be Taken if Material is Released or Spilled
Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations. Keep in suitable, closed containers for disposal.

D. Storage And Handling

General Handling
Avoid contact with skin and eyes, Avoid inhalation of vapour or mist. No smoking.

Other Handling Precautions
Keep away from sources of ignition. Take measures to prevent the build-up of electrostatic charge.

Storage
Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Storage under nitrogen if necessary.

Sensitive to light. Store in light-resistant containers.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Australia: No specific exposure standards are available.

The chemical has an exposure standard of 5 mg/m3 time weighted average (TWA) in Bulgaria, Hungary, Latvia and Russia; 10 mg/m3 in Poland; and 2 ppm in the USA.

Short-term exposure limits (STEL) of 4 ppm in the USA and Canada; 10 mg/m3 in Hungary; and 40 mg/m3 in Poland have been reported.

Engineering Controls
Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value. Ensure that eyewash stations and safety showers are proximal to the work-station location.

Personal Protection Equipment

Respiratory Protection:
Vapor respirator

Hand Protection:
Impervious gloves. Inspect gloves before use.

Skin Protection:
Protective clothing as required by the situation.

Eye protection*:*
Splash goggles or face shield and safety glasses

Other Precautions:
Use other PPE as required by the situation.

F. Transport Information

UN Number: 1990
Class 9

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

BISMUTH OXIDE

This dossier on bismuth oxide presents the most critical studies pertinent to the risk assessment of bismuth oxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): [(oxobismuthanyl)oxy]bismuthanone

CAS RN: 1304-76-3

Molecular formula: Bi2O3

Molecular weight: 465.96 g/mol

Synonyms: Dibismuth trioxide, Bismuth sesquioxide, Bismuth trioxide, Bismuthous oxide, Wismutoxid

SMILES: O=[Bi]O[Bi]=O

II. PHYSICAL and CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Bismuth Oxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Yellow monoclinic crystals or a yellow powder with no odor.	2	ECHA
Melting point	825°C	2	ECHA
Boiling point	1,890°C	2	ECHA
Density	8.93 g/cm^3 @ 20°C	2	ECHA
Water solubility	Slightly soluble. See below*	1	ECHA

*5.887 and 0.777 mg/L @ 21.3°C at a flow rates of 23.45 12.33/6.15 mL/hour, respectively. Measurements were bismuth oxide in water.

III. ENVIRONMENTAL FATE PROPERTIES

Biodegradation is not applicable to bismuth oxide. It is an inorganic mineral that is slightly soluble in water; thus, it is not expected to be bioaccumulative.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Bismuth oxide is not acutely toxic via oral, dermal or inhalation route or irritating to the skin or eyes. The findings indicate that it does not need to be classified as a skin sensitizer. There were no findings of toxicity in repeated dose testing. Bismuth is not expected to be genotoxic or carcinogenic, as oxides of bismuth are not soluble and testing with soluble bismuth salts were not found to be genotoxic. There are no reported reproductive or developmental effects for bismuth.

B. Acute Toxicity

Bismuth oxide is not acute toxic via oral, dermal or inhalation route. A 28-day oral gavage administration study in rats (Kl =2) found no mortality, abnormal clinical signs, body weight changes or abnormal histopathological findings at a maximum dose of 2000 mg/kg bw for both sexes (Sano et al., 2005).

Administration of a dry aerosol of dibismuth trioxide at a gravimetricly determined concentration of 5.07±0.09 mg dibismuth trioxide/L air for 4 hours by inhalation using a dynamic nose-only exposure chamber to rats found no mortality or change in weight gain over the course of the study. Slight ataxia and slight dyspnea was noted in 2 of 3 male and 3 of 3 female rats.

No studies were listed to evaluate the dermal toxicity of bismuth oxide.

C. Irritation

Dibismuth trioxide is not considered to be irritating to skin or to eyes. Dibismuth trioxide was tested for its potential to induce skin irritation in a human skin model (Kl =1). 3 tissues of the human skin model EpiSkin™ were treated with either the test item, the negative or the positive control for 15 minutes. 15 µL of either the negative control (deionised water) or the positive control (5% Sodium lauryl sulfate) were applied to each tissue. The test item is not considered to possess an irritant potential. In this study and under the experimental conditions reported, the test item was concluded to be a non-irritant to skin.

D. Sensitization

No published data or studies for determination the sensitisation properties of dibismuth trioxide are available. In an available guideline study with the more bioavailable substance, bismuth hydroxide nitrate oxide, the sensitising potential was determined in the LLNA in mice. Results show that bismuth hydroxide nitrate oxide does not reveal any sensitising properties and should not be classified and labelled according to regulation (EC) No.1272/2008. Based on read across from this much more bioavailable substance, it can be considered that dibismuth trioxide does not need to be classified for sensitisation.

E. Repeated Dose Toxicity

A 90-day repeated dose oral toxicity study (Kl = 2) was conducted in accordance with OECD Guideline 408 with the read-across substance, bismuth subnitrate. There was no adverse effect of treatment on body weight development and dietary intake in animals of either sex. Hematology, blood chemistry, testosterone hormone assessment, estrus cycle assessment in females, sperm analysis in males and microscopic examination of the selected tissues did not identify any findings of toxicological relevance. A dose level of 1000 mg/kg bw/day is therefore considered to be the NOAEL for systemic toxicity within the confines of this type of study. Based on read across to the results of this study, classification for repeated dose toxicity under the CLP Regulation is not required.

No reliable or relevant studies or data are available for dibismuth trioxide. Dermal repeated dose toxicity is considered to be scientifically unjustified. No data are available; classification concerning repeated dermal toxicity is not required.

F. Genotoxicity

No published data or studies for determination the mutagenicity of dibismuth trioxide is available. Due to the low solubility of the substance in water, it would not allow a study to be conducted in accordance with guidelines. However, there are publications available in which soluble bismuth salts were tested. Colloidal bismuth subcitrate was tested to induce sister chromatid exchanges or chromosome aberrations and bismuth subsalicylate and bismuth nitrate were both tested to induce gene mutation in bacterial cells. There is no indication for genotoxic/mutagenic effects of either colloidal bismuth subcitrate, bismuth subsalicylate or bismuth nitrate in these available publications.

In addition, in an available guideline study with the soluble bismuth hydroxide nitrate oxide the gene mutation potential was determined in the hprt locus of L5178Y mouse lymphoma cells. The study included treatments up to the maximum practicable concentration, 140 µg/mL (limited by solubility in the primary vehicle), in two independent experiments in the absence and presence of a rat liver metabolic activation system (S9).

G. Carcinogenicity

There are no studies available to evaluate carcinogenicity of bismuth oxide. Based on the lack of genotoxicity of soluble bismuth salts and the general insolubility of bismuth oxide, it is likely that bismuth oxides are not carcinogenic.

H. Reproductive and Developmental Toxicity

In a 90 day repeated dose oral toxicity study with additional reproductive toxicity endpoints conducted in accordance with OECD Guideline 408, the read-across substance, bismuth subnitrate had no toxicological effects on sperm or on testosterone levels in male rats or on the estrous cycle in female rats. The NOAEL in this study was 1000 mg/kg bw/day. By read across, dibismuth trioxide is not predicted to have any toxic effects on fertility.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for bismuth oxide follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from the available studies is 1000 mg/kg-day based on a lack of effect on clinical signs and mortality, body weight, haematology, clinical chemistry and other clinical endpoints. This NOAEL for bismuth oxide was adjusted using the molecular weight of bismuth oxide (466 g/mol, Bi2O3) and the molecular weight of bismuth subnitrate (397 g/mol, BiH2N3O9), resulting in a NOAEL of 1174 mg/kg-day. The NOAEL of 1174 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3

UF_D (database uncertainty) = 1
Oral RfD = 1174/(10 x 10 x 1 x 3 x 1) = 1174/300 = 4 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (4 x 70 x 0.1)/2 = 14 mg/L

B. Cancer

Bismuth oxide is not a carcinogen, therefore no drinking water guideline for cancerous endpoints is developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Bismuth oxide does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

While there are no aquatic toxicity studies on bismuth oxide, studies with bismuth subnitrate suggest a relatively low order of aquatic toxicity for bismuth compounds.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on bismuth subnitrate.

Table 2: Acute Aquatic Toxicity Studies on Bismuth Subnitrate ($Bi_5O(OH)_9(NO_3)_4$)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Brachydanio rerio	96-hr LC_{50}	>137 [WAF] >100 [WAF]*	2	ECHA
Daphnia magna	48-hr EC_{50}	>137 [WAF] >100 [WAF]*	2	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	>137 [WAF] >100 [WAF]*	2	ECHA

*As bismuth. The value for bismuth oxide is 223 mg/L (the molecular weight is 266 g/mol).

Chronic Studies
No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for bismuth oxide follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results on bismuth subnitrate are available for three trophic levels. Acute $E(L)C_{50}$ values (as bismuth oxide) are available for fish (>223 mg/L WAF), invertebrates (>223 mg/L WAF), and algae (>223 mg/L WAF). On the basis that the data consists of short-term data for three trophic levels, an assessment factor of 100 has been applied to the $E(L)C_{50}$ values of 223 for fish, invertebrates, and algae. The $PNEC_{water}$ is 2.2 mg/L (for bismuth oxide).

PNEC soil
There are no toxicity data for terrestrial or soil organisms. The $PNEC_{soil}$ cannot be derived using the equilibrium partitioning method.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Bismuth oxide is an inorganic mineral. Biodegradation is not applicable to bismuth oxide. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to bismuth oxide.

Bismuth oxide is an inorganic substance that is a slightly soluble powder. Bioaccumulation of bismuth oxide is generally unlikely to occur, given its low bioavailability.

There are no chronic toxicity studies on bismuth oxide. The acute E(L)C_{50} values of another inorganic bismuth substance (bismuth subnitrate) are >1 mg/L for fish, invertebrates, and algae. Thus, bismuth oxide is not expected to meet the criteria for toxicity.

The overall conclusion is that bismuth oxide is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

This substance does not meet the criteria for classification in accordance with Regulation No 1272/ 2008/EC. It Is not a dangerous substance or mixture according to the Globally Harmonized System (GHS).

B. Labelling

Not required. This substance does not meet the criteria for classification; it is not a dangerous substance according to the Globally Harmonized System.

C. Pictogram

Not required.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Skin Contact
Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

Inhalation
Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

Ingestion
Rinse mouth. Call a doctor if you feel unwell.

Notes to Physician
Treat symptomatically.

Medical Conditions Aggravated by Exposure
No data available.

Emergency Personnel Protection
No data available.

B. Fire Fighting Information

Extinguishing Media
Co-ordinate fire-fighting measures to the fire surroundings; water spray, foam, dry extinguishing powder, carbon dioxide (CO2). Keep product and empty container away from heat and sources of ignition.

Specific Exposure Hazards
No data available.

Special Protective Equipment for Firefighters
Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Do not breathe dust; avoid dust formation.

Environmental Precautions
Keep away from drains, surface and ground water.

Steps to be Taken if Material is Released or Spilled
Stop leak if possible without risk. Take up mechanically. Clean contaminated surface.

D. Storage and Handling

General Handling
Wear personal protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid ingestion and inhalation. Avoid dust formation.

Other Handling Precautions
Keep away from incompatible materials.
Incompatible materials: Strong oxidizing agents

Storage
Keep containers tightly closed in a dry, cool and well-ventilated place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
No data available. Bismuth oxide is not listed among Safe Work Australia Hazardous Chemicals. No exposure controls for bismuth oxide are presented on the ECHA site.[1]

Engineering Controls
Ensure adequate ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to manage airborne levels. If user operations generate dust, fume or mist, use ventilation and/or respiratory protection

Personal Protection Equipment
Respiratory Protection:
Effective dust mask. Use a dust respirator under conditions where exposure to the substance is apparent (e.g. generation of high concentration of dust (dust clouds), inadequate ventilation, development of respiratory tract irritation), and engineering controls are not feasible. Be sure to use an approved/certified respirator or equivalent.

Hand Protection:
Appropriate gloves; inspect before use.

Skin Protection:
Loved sleeved clothing, chemical resistant apron.

Eye protection:
Safety glasses with side-shields.

[1] Substance is known to be on the EEA market in nanomaterial form, as listed in the EUON Nanomaterials in the EU market list.

Other Precautions:
Regular hygiene: Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product When using, do not eat, drink or smoke.

F. Transport Information

UN Number: Not regulated

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

BUTYL ALCOHOL (1-BUTANOL)

This dossier on butyl alcohol (1-butanol) presents the most critical studies pertinent to the risk assessment of 1-butanol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997; Kl).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Butan-1-ol

CAS RN: 71-36-3

Molecular formula: C4H10O

Molecular weight: 74.123

Synonyms: 1-Butanol, 1-Butyl alcohol, 1-hydroxybutane, Butan-1-ol, butyl alcohol, Butyl hydroxide, Butylalcohol, CCS 203, ET5740PTB, Hemostyp, Methylolpropane, n-Butanol, n-Butyl alcohol, N300PTB, Nacol 4, PP100, Propylcarbinol

SMILES: CCCCO

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of 1-Butanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, colorless liquid with an alcoholic odor	2	ECHA
Melting point	<-90°C	2	ECHA
Boiling point	119°C	2	ECHA
Density	0.81 g/cm^3 @ 20°C	2	ECHA
Vapor pressure	< 10 hPa @20°C	2	ECHA
Partition coefficient (log K_{ow})	1 @ 25°C	1	ECHA

Property	Value	Klimisch score	Reference
Water solubility	66 g/L @ 20°C	1	ECHA
Flash point	35°C	2	ECHA
Auto flammability	355°C	1	ECHA
Viscosity	2.947 mPa s @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

1-Butanol is readily biodegradable and not expected to bioaccumulate. No experimental data are available for adsorption/desorption; the estimated Koc value is 3.471 L/kg.

A calculated log Koc of 0.54 is available, suggesting a high mobility of 1-butanol in soil.

B. Biodegradation

1-Butanol is readily biodegradable. In a BOD test, degradation was 87% after 10 days and 92% after 20 day, meeting the 10-day window (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for 1-butanol. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} of 1.0 is 10.01 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 3.471 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on 1-butanol. 1-Butanol is not expected to bioaccumulate based on a log K_{ow} of 1.0 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Butyl alcohol is slightly acutely toxic to experimental animals via the oral and dermal routes of exposure; a low acute toxicity was observed after inhalative exposure. The chemical is classified in Australia as respiratory system and skin irritant but is not

considered a skin sensitiser. Butyl alcohol is not expected to be genotoxic; although there are no data on the carcinogenicity of butyl alcohol, based on the lack of genotoxicity, it is not expected to be. Few studies have evaluated reproductive or developmental toxicity but the available studies do not indicate reproductive or developmental effects. Any developmental toxicity is expected to be secondary to maternal toxicity.

B. Acute Toxicity

Butyl alcohol is slightly acutely toxic to experimental animals via the oral and dermal routes of exposure; a low acute toxicity was observed after inhalative exposure.

Oral

The most sensitive LD50 value was provided by a study comparable to OECD TG 401 (Union Carbide Corporation 1967). Here, 60 -day-old female Harlan Wistar rats were dosed with butan-1 -ol at various dose levels per gavage. The acute LD50 value was 2.83 mL/kg bw in female rats, corresponding to 2290 mg/kg bw (calculated with a density of 0.81 g/mL). No further data were available.

A comparable LD50 level was observed in a study following the standard acute method with acceptable restrictions (Jenner et al.1967). In this study, 5 young adult Osborne-Mendel rats per sex were dosed with butan-1-ol at different, but unspecified doses. The rats were observed for 14 days and the LD50 values were calculated. After 14 d observation period, the LD50 was 2510 mg/kg bw in rats. Mortality occurred within 4 - 18 h after dosing, and depression and coma were reported as clinical signs. Weighing and performance of necropsy was not reported.

In another oral acute study, groups of 10 female rats were orally gavaged with 3160, 3980, 5000 or 6300 mg/kg and observed for 14 days after dosing. Here, 0, 3, 8 and 10 rats died at dose levels of 3160, 3980, 5000 or 6300 mg/kg, respectively. Deaths following oral doses occurred in many cases within 4 hours and in all but one instance within 24 hours. The LD50 was 4360 mg/kg/bw for female rats (Union Carbide Corporation 1951).

For other common test species oral LD50 values were reported with limited details: 2680 mg/kg bw for mice (Rumyanstev et al., 1979, Val. 4), 3500 mg/kg bw for rabbits (Munch, 1972; Munch and Schwarze, 1925, Val. 4), 1200 mg/kg bw for Golden hamsters (Dubina and Maksimov, 1976, Val. 4), and a minimum lethal dose of 1782 mg/kg bw for dogs (Von Oettingen, 1943, Val. 4). In the ECETOC JACC (2003) document also one publication with an oral LD50 in rats below 2000 mg/kg (790 mg/kg) is reported.

Dermal

The most reliable data were provided by a study comparable to OECD TG 402 (Union Carbide Corporation 1951). Here, butan-1 -ol was applied to the shaved skin of rabbits

for 24 hours under occlusive conditions. Four doses of 1.26 to 10 ml/kg were applied to groups of four male rabbits and a LD50 value of 4.24 ml/kg bw (corresponding to ca. 3434 mg/kg bw; calculated with a density of 0.81 g/mL) was determined after an observation period of 14 days. Three rabbits of the 5 mL/kg bw group and all rabbits of the 10 ml/kg bw group died; all deaths occurred on the day of application. Body weight gain during the observation period was highly variable in the sublethal dose groups and negative in the survivor of the 5 mL/kg bw group. No information regarding clinical signs or local effects was available. In the ECETOC JACC (2003) document further dermal LD50 values in rabbits of 7600, 5300 and 4200 mg/kg are reported.

Inhalation

In a study similar to OECD TG 403, 10 Sprague-Dawley rats per sex per dose were whole-body exposed to vapour atmospheres of butan-1-ol for 4 h and observed for 14 d. The LC0 is >17.76 mg/L; no mortality or clinical signs were observed at 17.76 mg/L; only slightly reduced body weight gain was observed. Therefore, the LD50 level is considered to be > 20 mg/L (BASF 1979).

In another study, which was similar to the inhalation hazard test of OECD TG 403, 12 Sprague-Dawley rats of both sexes were exposed to a vapour saturated butan-1-ol atmosphere for 7 h. None of the animals died (BASF 1980).

Additionally, in a further study comparable to OECD TG 403 no mortalities were observed after exposure to a substantially saturated vapour for 8 hours in male rats and after exposure to 8000 ppm (ca. 24 mg/L) for 4 h in female rats, respectively. Poor coordination or prostration was observed in both trials (Union Carbide Corporation 1951).

C. Irritation

Respiratory Irritation

The chemical is classified in Australia as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (Safe Work Australia). The available data from observations in animals and humans support this classification.

Based on an inhalation study in mice, it was reported that 1268 ppm (3909 mg/ m^3) of the chemical was predicted to be intolerable in humans, 127 ppm (390.9 mg/ m^3) would be uncomfortable in humans and 13 ppm (40 mg/ m^3) was expected to have no effect on humans (OECD 2001).

Skin Irritation

The chemical is classified in Australia as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). The available data from observations in animals and humans support this classification.

Moderate irritation was reported in a 24 hour patch test (non-guideline study) where 405 or 500 mg of the chemical was applied to the skin of the rabbits. It was reported that these effects may be due to the chemical's defatting (chemical dissolving of dermal lipids from the skin) and drying characteristics (OECD 2001).

Another non-guideline study reported the chemical was a skin irritant in several Vienna white rabbits exposed to 0.5 mL of the chemical for five minutes, one hour or two hours under occlusive conditions. The animals were observed for eight days. The authors concluded that exposure for two hours under occlusive conditions resulted in higher Draize scores and observed superficial necrosis (death of tissue). However, there was no full thickness destruction of the skin (REACH).

Eye Irritation

The chemical is classified in Australia as hazardous with the risk phrase 'Risk of serious damage to the eyes' (Xi; R41) in HSIS (Safe Work Australia). The available data from observations in animals and humans support this classification.

The chemical was reported to be a severe eye irritant when tested according to OECD Test Guideline (TG) 405 using 0.1 mL of the chemical applied to three New Zealand white rabbits. Severe ocular lesions were present at the end of the seven-day observation period, indicating severe eye damage and irreversible effects on the eye (REACH).

The chemical was reported to be a severe eye irritant in rabbits in non-guideline studies where 1.62 or 20 mg of the chemical was applied into rabbit eyes over a 24 or 72 hour period (OECD 2001). An additional non-guideline study reported severe corneal irritation when 0.005 mL of the chemical was applied into rabbit eyes.

D. Sensitization

Based on available repeat dose dermal studies, the chemical is not expected to be a skin sensitiser. OECD (2001) reported that human studies and experience show that the chemical is not likely to be a skin sensitiser.

E. Repeated Dose Toxicity

Oral

A no observed adverse effect level (NOAEL) of 125 mg/kg bw/day and a lowest observed adverse effect level (LOAEL) of 500 mg/kg bw/day in male and female CD rats was reported based on results from a repeat dose oral study (Kl = 1) using the chemical (OECD 2001). Groups of male and female rats (30/sex/group) were administered the chemical via gavage at 0, 30, 125 or 500 mg/kg/day for 13 weeks. It was reported that ataxia (impaired muscle coordination) and hypoactivity were observed at the highest

dose during the final six weeks of the study. No treatment related effects were reported in the 30 and 125 mg/kg/ bw/day dose groups (OECD 2001).

Inhalation

In a non-guideline study, the chemical was applied to the skin of rabbits under occlusive conditions over a period of 21 days. Local effects were reported such as drying of the skin, cracking, wrinkling and exfoliation of the epidermis. However, no systemic toxicity was reported (REACH). In another non-guideline repeat dose dermal study on rabbits, 42 to 55 mL/kg of the chemical applied to the skin of rabbits over four consecutive days resulted in 100 % mortality. However, the same study reported that 30 applications of 20 mL/kg of the chemical over six weeks did not produce any deaths (OECD 2001).

Dermal

No data are available.

F. Genotoxicity

The chemical is not expected to be genotoxic.

The chemical tested negative in a number of tests for genotoxicity. These included several in vitro tests (OECD Guideline 473: mammalian chromosome aberration test on Chinese hamster lung fibroblasts V79; OECD Guideline 471: bacterial reverse mutation assay on *S. typhimurium* TA 98, TA 100, TA 98, TA 1535 and TA 1537; OECD Guideline 476: mammalian cell gene mutation test on Chinese hamster lung fibroblasts V79) and in vivo tests (OECD Guideline 474: mouse micronucleus) (OECD 2001, REACH).

In Vitro Studies

Table 2: *In vitro* Genotoxicity Studies on

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium strain TA 98, TA 100, TA 98, TA 1535 and TA 1537)	-	-	2	Jung et al., 1992
Mammalian cell gene mutation (Chinese hamster lung fibroblasts (V79))	-	-	1	REACH

*+, positive; -, negative

In Vivo Studies

Fewer studies are available for in vivo testing but are also negative for genotoxicity. According to the results of a reliable mouse study conducted according to OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) (Kl =1), the single oral

administration of butan-1-ol did not lead to any increase in the number of polychromatic erythrocytes containing either small or large micronuclei. The rate of micronuclei was always in the same range as that of the negative control in all dose groups and at all sacrifice intervals. No inhibition of erythropoiesis determined from the ratio of polychromatic to normochromatic erythrocytes was detected.

G. Carcinogenicity

OECD (2001) reported that based on the number of negative mutagenicity and clastogenicity findings, the chemical is not expected to be a carcinogen. A weight of evidence study reported that the chemical is not expected to have carcinogenic potential as it does not contain structural components to support carcinogenicity (REACH, HSDB).

H. Reproductive and Developmental Toxicity

The chemical is not expected to be toxic to reproduction (OECD 2001). In a non-guideline study, male and female Sprague Dawley (SD) rats were exposed to the chemical via inhalation at 0, 3000 or 6000 ppm for seven hours/day. Female rats were exposed to the chemical throughout gestation, while males were exposed to the chemical for six weeks prior to mating. No harmful effects on fertility or pregnancy rate were reported at any of the dose levels. In another non-guideline study, no testicular toxicity (effect on testes weight or histopathology) was reported in SD male rats that were administered the chemical via oral intubation at 533 mg/kg bw/day over six days (OECD 2001).

Any developmental effects were only reported to be observed secondary to maternal toxicity, so the chemical is not expected to be a developmental toxin. OECD (2001) reported that the chemical showed mild foetotoxicity and developmental variations in offspring only at or near the maternally toxic and, in some cases, lethal dose of 8000 ppm. Offspring of female SD rats exposed via inhalation to 0, 3500, 6000 or 8000 ppm of the chemical on gestations days 1 to 19, reported a reduction of foetal weights at 6000 and 8000 ppm and a slight increase in skeletal malformations at 8000 ppm but not at the lower dosage levels. At a maternally toxic dose of 8000 ppm, decreased weight gain, food consumption and dam deaths were reported. The NOAEL for offspring and dams was 3500 ppm as there was a slight decrease in foetal weight at the 6000 ppm dose level.

In another 20 day study in male and female SD rats exposed to 0, 3000 or 6000 ppm of the chemical via inhalation, a small number of behavioural and neurochemical variations in offspring at 6000 ppm were reported. No maternal toxicity was reported throughout gestation for females or for six weeks prior to mating for males as a result of maternal or paternal exposure. However, the effects observed in offspring were not regarded as

biologically significant by the authors due to inconsistences between dose-response patterns.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for butyl alcohol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is 125 mg/kg-day based on CNS effects in rats from a 90-day oral gavage study (Kl = 1; REACH). The NOAEL of 125 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 125/(10 x 10 x 1 x 3 x 1) = 125/300 = 0.4 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.4 x 70 x 0.1)/2 = 1.4 mg/L

B. Cancer

No human and no animal cancer data are available. As such, the substance is not classifiable as to human carcinogenicity according to guidelines provided by the World Health Organization (WOE).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

1-Butanol is a flammable liquid.

1-Butanol does not exhibit the following physico-chemical properties:

· Explosivity
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is exhibits a low order of acute and chronic aquatic toxicity as demonstrated by the information provided below.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on 1-butanol.

Table 3: Acute Aquatic Toxicity Studies on 1-Butanol.

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephelas promelas	96-hr LC_{50}	1,376	1	ECHA
Daphnia magna	48-hr EC_{50}	1,328	1	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	225	1	ECHA

Chronic Studies

The 21-d NOEC from a *Daphnia* reproduction test is 4.1 mg/L (ECHA) [Kl. score = 2].

96-hr EC_{10} to *Pseudokirchneriella subcapitata* is 134 mg/L (ECHA) [Kl. score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for 1-butanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (1,376 mg/L), invertebrates (1,328 mg/L), and algae (225 mg/L). Results from chronic studies are available for invertebrates (4.1 mg/L) and algae (124 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term studies for two trophic levels, an assessment factor of 50 has been applied to the lowest reported EC_{10} value of 4.1 mg/L for fish. The $PNEC_{water}$ is 0.08 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.004 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.07/1500) \times 1000 \times 0.08$
$= 0.004$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 3.471 \times 0.02$
$= 0.07$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for 1-butanol based on the molecular connectivity index (MCI) is 3.471 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

1-Butanol is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 1.0, 1-butanol does not meet the screening criteria for bioaccumulation.

The lowest chronic EC_{10} or NOEC value for 1-butanol is >0.1 mg/L. The acute $E(L)C_{50}$ values are >1 mg/L. Thus, 1-butanol does not meet the criteria for toxicity.

The overall conclusion is that 1-butanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable liquid Category 3
Acute toxicity Category 4
Specific target organ toxicity Category 3
Skin irritation Category 2
Eye damage Category 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>

Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do so. Continue rinsing. Call physician or poison center.

Skin Contact
Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

Inhalation
Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Ingestion
Call physician or poison center.

Notes to Physician
May cause drowsiness or dizziness

Irritating to eyes, respiratory system and skin. Central nervous system effects. Hearing impairment Treat symptomatically.

Medical Conditions Aggravated by Exposure
No data available

Emergency Personnel Protection
First-Aid Providers: Avoid exposure to blood or body fluids. Wear gloves and other necessary protective clothing. Dispose of contaminated clothing and equipment as bio-hazardous waste.

B. Fire Fighting Information

Extinguishing Media
Use foam, dry chemical, CO2 or water spray for extinction. Alcohol-resistant Foam; butanol is an alcohol. Do not use a solid (straight) water stream as it may scatter and spread fire.

Specific Exposure Hazards
Combustion products include carbon monoxide and carbon dioxide. Flammable. May be ignited by heat, sparks or flames. Material can burn with invisible flame. Vapor may travel considerable distance to source of ignition and flash back.
Vapors may form explosive mixtures with air. Most vapors are heavier than air. They will spread along the ground and collect in low or confined areas (sewers, basements, tanks). Container explosion may occur under fire conditions or when heated. Fire may produce irritating, corrosive and/or toxic gases.

Special Protective Equipment for Firefighters
Wear SCBA and fully encapsulating, gas-tight suit when handling these substances. Structural firefighter's uniform is NOT effective for these materials.

C. Accidental Release Measures

Personal Precautions
Ensure adequate ventilation. Keep people away from and upwind of spill/leak. Avoid contact with skin, eyes and clothing. Use personal protective equipment. Remove all sources of ignition. Pay attention to flashback. Take precautionary measures against static discharges. All equipment used when handling the product must be grounded. Use spark-proof tools and explosion-proof equipment. In case of large spill, water spray or vapor-suppressing foam may be used to reduce vapors, but may not prevent ignition in closed spaces.

Environmental Precautions
Prevent further leakage or spillage if safe to do so. Prevent product from entering drains. Prevent entry into waterways, sewers, basements or confined areas. In case of large spill, dike if needed. Dike far ahead of liquid spill for later disposal.

Steps to be Taken if Material is Released or Spilled
Stop leak if you can do it without risk. Absorb spill with inert material (e.g. vermiculite, dry sand or earth).
Use appropriate tools to put the spilled material in a suitable chemical waste disposal container. Use clean non-sparking tools to collect absorbed material.
Clean contaminated surface thoroughly.

D. Storage and Handling

General Handling
Wear personal protective equipment. Use only in well-ventilated areas. Avoid contact with skin, eyes and clothing.
Keep away from heat and sources of ignition. Do not breathe vapors or spray mist. Do not ingest. When using do not smoke. Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions
Remove all sources of ignition. To avoid ignition of vapors by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from incompatible materials.

Storage

Keep container tightly closed in a dry and well-ventilated place. Store at room temperature in the original container. Keep away from heat and sources of ignition. Store in a segregated and approved area. Store away from incompatible materials. Incompatible Materials: Oxidizing agents, Acids, Alkali Metals, Halogens, Aluminum, Caustics, isocyanates

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for butanol in Australia is 152 mg/m3 as an 8-hr TWA. No STEL is listed.

Engineering Controls
Ensure adequate ventilation. Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors and mist below their respective threshold limit value.

Personal Protection Equipment
Respiratory Protection:
Where ventilation is not adequate, respiratory protection may be required. Avoid breathing vapours or mists. Select and use respirators appropriately. When mists or vapours exceed the exposure standards then the use of the following is recommended: Approved respirator with organic vapour and dust/mist filters. Filter capacity and respirator type depends on exposure levels.

Hand Protection:
Use appropriate, impervious gloves. Inspect gloves before use.

Skin Protection:
Chemical resistant apron, long sleeved clothing

Eye protection:
Use face shield, chemical goggles or safety glasses with side shield protection as appropriate.

Other Precautions:
No additional notes available.

F. Transport Information

UN Number 1120
Hazard class 3

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

HYDROCARBONS, C12-C15, N-ALKANES, ISOALKANES, CYCLICS, <2% AROMATICS

This dossier on hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics (C12-C15 aliphatic hydrocarbons (<2% aromatics)) presents the most critical studies pertinent to the risk assessment of C12-C15 aliphatic hydrocarbons (<2% aromatics) in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics

CAS RN: 64742-47-8 [CAS No. 869062-45-3; EC No. 920-107-4]

Historically, hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2%aromatics was included within the CAS RN 64742-47-8 for distillates, (petroleum), hydrotreated, light. This CAS RN is broadly defined as "A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon number predominantly in the range of C9 to C16 and boiling in the range of approximately 150°C to 290°C (302° to 554°F)." This CAS RN can include hydrocarbon streams and solvents that can vary widely in their compositions, processing, and classifications. The EU Hydrocarbon Solvents Producers Association (HSPA), for the purposes of REACH registrations, established more precise definitions for hydrocarbon solvents and established a new substance identification and naming convention.[1] Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, < 2% aromatics would have the CAS RN 869062-45-3 and EC. No. 920-107-4 and would be within the HSPA category for C9-C14 Aliphatics (≤2% aromatics).

Molecular formula: Not available (UVCB substance)

Molecular weight: Not available (UVCB substance)

Synonyms: Hydrocarbons, C12-C15, n-alkanes, isoalkanes, cyclics, <2% aromatics; distillates, petroleum, hydrotreated, light; C12-C15 aliphatic hydrocarbons (<2% aromatics)

SMILES: Not available (UVCB substance)

[1] https://www.reachcentrum.eu/Consortia%20Documents/P-I163/Other/20110401160024-HSPA_CAS_April__2011.pdf.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of C12-C15 Aliphatic Hydrocarbons (<2% Aromatics)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless to faint yellow with a slight odor.	2	ECHA
Melting point	-30°C	2	ECHA
Boiling point	233 to 266°C	2	ECHA
Density	0.79 to 0.85 g/cm^3 @ 15°C	2	ECHA
Vapor pressure	0.003 kPa @ 20°C (calculated)	2	ECHA
Partition coefficient (log K_{ow})	Not determined (UVCB substance)	-	-
Water solubility	Not determined (UVCB substance)	-	-
Flash point	102°C	2	ECHA
Auto flammability	>200°C	2	ECHA
Viscosity	3.56 mm^2/s @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

There are no biodegradation data on C11-C15 aliphatic hydrocarbons (<2% aromatics). However, a hydrocarbons, C11-14, n-alkanes, isoalkanes, cyclics (<2% aromatics) hydrocarbon fluid was shown to be readily biodegradable. The C12-C15 aliphatic hydrocarbons (<2% aromatics) are expected to highly absorb to sediment and soil. The C12-C15 aliphatic hydrocarbons (<2% aromatics) is expected to have constituents with the potential to bioaccumulate.

B. Biodegradation

No biodegradation data are available on C12-C15 aliphatic hydrocarbons (<2% aromatics).

In an OECD 301F test, degradation of hydrocarbons, C11-14, n-alkanes, isoalkanes, cyclics (<2% aromatics) hydrocarbon fluid was 69% after 28 days (ECHA) [Kl. score = 1]. The results indicate

that this substance is readily biodegradable even though it did not meet the 10-day window because the criterion does not apply to multi-component substance when assessing their ready biodegradability (ECHA) [Kl. score = 1].

C. Environmental Distribution

C12-C15 aliphatic hydrocarbons (<2% aromatics) and C9-C14 aliphatic hydrocarbons (≤2% aromatics) are UVCB substances. The standard tests to determine the K_{oc} are for single substances and not for UVCB substances. Therefore, a K_{oc} value for C12-C15 aliphatic hydrocarbons (<2% aromatics) was not determined.

The calculate K_{oc} values for linear aliphatic hydrocarbons dodecane (C12) and tetradecane (C14) are 110,000 and 759,000 L/kg, respectively, using SPARC v4.2 program in the Concawe Library of Petrorisk (ECHA). These values suggest that C12-C15 aliphatic hydrocarbons (<2% aromatics) will highly absorb to sediment and soil.

D. Bioaccumulation

C12-C15 aliphatic hydrocarbons (<2% aromatics) and C9-C14 aliphatic hydrocarbons (≤2% aromatics) are UVCB substances. The calculated BCF values for linear aliphatic hydrocarbons undecane (C11), dodecane (C12), and tetradecane (C14) are 337.8, 790.9, and 962.9 L/kg, respectively using the BCFWIN V2.16 model within EPISuite 3.12. The predicted BCFs for hydrocarbons are considered to be generally overly conservative because biotransformation is not quantitatively taken into account. For these linear aliphatic hydrocarbons, the values indicate that they are not expected to bioaccumulate. However, both C12-C15 aliphatic hydrocarbons (<2% aromatics) and C9-C14 aliphatic hydrocarbons (≤2% aromatics) contain branched and cyclic aliphatic hydrocarbons that are expected to have a greater potential to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of C9-C14 aliphatic hydrocarbons (≤2% aromatics) is low by the oral, dermal, and inhalation route. It is, however, an aspiration hazard. C9-C14 aliphatic hydrocarbons (≤2% aromatics) are neither skin nor eye irritants or a dermal sensitizer. Repeated inhalation exposure of rats to a C9-C14 aliphatic (≤2% aromatic) hydrocarbon fluid showed no target organ effects; oral exposures to very high doses of these hydrocarbons showed irritation to the gastrointestinal tract and effects in the liver that likely represent an adaptive response to the metabolism of the hydrocarbons and not a toxic response. C9-C14 aliphatic hydrocarbons (≤2% aromatics) are not genotoxic; nor do they exhibit and evidence of reproductive or developmental toxicity in rats.

B. Acute Toxicity

The oral LD_{50} in rats for C9-C14 aliphatic, ≤2% aromatic hydrocarbon fluids is >5,000 mg/kg (ECHA) [Kl. score = 2.

The 4-hour inhalation LC_{50} in rats for C9-C14 aliphatic, ≤2% aromatic hydrocarbon fluids is > 4,951 mg/m^4 (ECHA) [Kl. scores =1 and 2].

The dermal LD_{50} in rats for C9-C14 aliphatic, ≤2% aromatic hydrocarbon fluids is >5,000 mg/kg (ECHA) [Kl. score = 2].

C. Irritation

C9-C14 aliphatic, ≤2% aromatic hydrocarbon fluids are neither skin nor eye irritants (ECHA) [Kl. scores = 1 and 2].

D. Sensitization

C9-C14 aliphatics, <2% aromatic hydrocarbon fluids were not skin sensitizers when tested in guinea pig maximization tests (ECHA) [Kl. score = 2].

A C9-C14 aliphatic, <2% aromatic hydrocarbon fluid showed no indication of skin sensitization in a human repeated insult patch test (ECHA).

E. Repeated Dose Toxicity

Oral

Male and female rats were dosed by oral gavage with 0, 500, 2,500 or 5,000 mg/kg with a C9-C14 aliphatic, <2% aromatic hydrocarbon fluid 7 days/week for 13 weeks. Additional groups of animals were dosed with 0 or 5,000 mg/kg for 13 weeks, followed by a 4-week recovery period. There were dose-related changes in the hematology and serum chemistry parameters which were consistent with changes seen in the liver. Hepatocellular hypertrophy (liver cell enlargement) were seen in both males and females in all dose groups and were reversible. The liver effects were not considered to be an indication of toxicity but an adaptive response due to the metabolism of the hydrocarbons. There were also mucosal thickening and other signs of irritation to the stomach and anus, which appeared to be the direct result of high-dose intubation of a locally irritating material. All treatment-related effects were reversible within the 4-week recovery period. The NOAEL for systemic effects in this study is considered to be 5,000 mg/kg-day (ECHA) [Kl. score = 1].

Inhalation

Male and female rats were exposed by inhalation to 0, 2,600, 5,200, or 10,400 mg/m^3 of a C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid, 6 hours/day, five days/week for 13 weeks. There was no mortality or effects in either the hematology or the serum chemistry parameters. The male rats at all dose levels had increased liver and kidney weights; male heart weights were also increased at 10,400 mg/m^3; and kidney weights were increased in the 10,400 mg/m^3 group. Kidney effects indicative of alpha-2u-globulin nephropathy was observed at all dose levels. There were no other effects that were considered to be treatment-related. The alpha-2u-nephropathy in the male rats was not considered to be relevant to humans; for the organ weight changes other than the male kidneys, there were no corresponding histopathologic changes. The NOAEL for this study is 10,400 mg/m^3, the highest exposure concentration tested (ECHA) [Kl. score = 1].

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

The key *in vitro* genotoxicity studies on C9-C14 aliphatic hydrocarbons (≤2% aromatics) are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on C9-C14 Aliphatic Hydrocarbons (≤2% Aromatics)

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Mammalian cell gene mutation (Chinese hamster V 79 cells)	-	-	2	ECHA
Chromosomal aberration (human lymphocytes)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

In two separate studies involving two different C9-C14 aliphatic (<2% aromatic) hydrocarbon fluids, male and female CD-1 mice were given a single oral gavage dose at concentrations of 0, 1,250, 2,500, or 5,000 mg/kg. The frequency of micronucleated polychromatic erythrocytes was not significantly increased in the treated mice compared to that in the controls (ECHA) [Kl. score = 1].

In two separate dominant lethal studies involving two different C9-C14 aliphatic (<2% aromatic) hydrocarbon fluids, male rats were exposed for 6 hours/day for five consecutive days to exposure concentrations of 0, 300, or 900 ppm. There was no evidence of a mutagenic response in the treated rats (ECHA) [Kl. score = 2].

G. Carcinogenicity

No carcinogenicity studies are available on the C9-C14 aliphatic (<2% aromatic) hydrocarbon fluids.

H. Reproductive Toxicity

A C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid was tested in a combined repeated dose toxicity study with a reproductive/developmental toxicity screening test (OECD 422). Male and female SD rats were given oral gavage doses of 0, 25, 150, or 1,000 mg/kg-day. There was no indication of reproductive toxicity at any dose level. The NOAEL for reproductive toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 1].

A C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid was tested in a reproductive/developmental toxicity screening test (OECD 421). Male and female SD rats given oral gavage doses of 0, 100, 300, or 1,000 mg/kg-day. There was no indication of reproductive toxicity or any effects on the endocrine system at any dose level. The NOAEL for reproductive toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 1].

I. Developmental Toxicity

A C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid was tested in a rat pre-natal developmental toxicity study. Pregnant female rats were exposed by inhalation to 0, 300 or 900 ppm for 6 hours/day during gestation days 6 to 15. There was no evidence of maternal or developmental toxicity at either exposure level. The NOAEL for this study is 900 ppm (ECHA) [Kl. score = 1].

Another C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid was tested in a rat pre-natal developmental toxicity study. Pregnant female rats were exposed by inhalation to 0, 300 or 900 ppm for 6 hours/day during gestation days 6 to 15. There was no evidence of maternal or developmental toxicity at either exposure level. The NOAEL for this study is 900 ppm (ECHA) [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for C12-C15 aliphatic hydrocarbons (<2% aromatics) follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>
A 13-week oral gavage study was conducted on a C9-C14 aliphatic (<2% aromatic) hydrocarbon fluid in rats. There were no adverse effects at 5,000 mg/kg-day, the highest dose tested. The NOAEL of 5,000 mg/kg-day will be used to derive the oral reference dose and the drinking water guidance value for C12-C15 aliphatic hydrocarbons (<2% aromatics).

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1

UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 5,000/(10 x 10 x 1 x 3 x 1) = 5,000/300 = 17 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (17 x 70 x 0.1)/2 = 60 mg/L

B. Cancer

No carcinogenicity studies are available on C9-C14 aliphatic (<2% aromatic) hydrocarbon fluids. Thus, a cancer reference value was not derived for C12-C15 aliphatic hydrocarbons (<2% aromatics).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

C12-C15 aliphatic hydrocarbons (<2% aromatics) do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

C12-C15 aliphatic hydrocarbons (<2% aromatics) has a low acute toxicity concern to aquatic life.

B. Aquatic Toxicity

Acute Studies

There are no aquatic toxicity data on C12-C15 aliphatic hydrocarbons (<2% aromatics). Table 3 lists the results of acute aquatic toxicity studies conducted on a C11-C14 aliphatic hydrocarbon fluid (<2% aromatics).

Table 3: Acute Aquatic Toxicity Studies on C11-C14 Aliphatic Hydrocarbon Fluid (<2% Aromatics)*

Test Substance	Test Species	Endpoint	Results (mg/L) [WAF]	Kl. score
C11-C14, n-alkanes, isoalkanes, cyclics (<2% aromatics)	*Oncorhynchus mykiss*	96-h LL_{50}	>1,000	1
C11-C14, n-alkanes, isoalkanes, cyclics (<2% aromatics)	*Daphnia magna*	48-h LL_{50}	>1,000	1
C11-C14, n-alkanes, isoalkanes, cyclics (<2% aromatics)	*Pseudokirchnerella subcapitata*	72-h LL_{50} 72-hr NOELR	>1,000	1

*All studies used the water accommodated fractions (WAFs) of the test substance.

Chronic Studies

The value for NOELRs were estimated by QSAR model – Petrotox. This model combines a partitioning model used to calculate the aqueous concentration of hydrocarbon components with the Target Lipid Model used to calculate acute and chronic toxicity of non-polar narcotic chemicals. Petrotox computes toxicity based on the summation of the aqueous-phase concentrations of hydrocarbon block(s) that represent a hydrocarbon substance and membrane-water partition coefficients that describe the partitioning of the hydrocarbons between the water and organisms.

The 28-day NOELR (No-Observed-Effect-Loading-Rate) for hydrocarbons, C12-15, aliphatic hydrocarbons (<2% aromatics) in freshwater fish is estimated to be >1,000 mg/L based on growth (ECHA) [Kl. score = 2].

The 28-day NOELR (No-Observed-Effect-Loading-Rate) for hydrocarbons, C12-15, aliphatic hydrocarbons (<2% aromatics) in freshwater invertebrates is estimated to be >1,000 mg/L based on reproduction (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for C12-C15 aliphatic hydrocarbons (<2% aromatics) follow the methodology:

PNEC water
Using the QSAR model PETRORISK v7.04, the estimated $PNEC_{water}$ value for C11-15-iso- is 0.001 mg/L (CONCAWE) [Kl. score = 2].

PNEC sediment
Using the QSAR model PETRORISK, v7.04 the estimated $PNEC_{sediment}$ value for C11-15-iso- range from 42 to 260 mg/kg soil wet weight (CONCAWE), depending on the composition of the hydrocarbon classes (n- or iso-paraffins and type of cyclic paraffins) (CONCAWE) [Kl. score = 2].

PNEC soil
Using the QSAR model PETRORISK v7.04, the estimated $PNEC_{sediment}$ value for C11-15-iso- is 17 to 100 mg/kg soil wet weight (CONCAWE), depending on the composition of the hydrocarbon classes (n- or iso-paraffins and type of cyclic paraffins) (CONCAWE) [Kl. score = 2].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Hydrocarbons, C11-14, n-alkanes, isoalkanes, cyclics (<2% aromatics) hydrocarbon fluid was readily biodegradable. Thus, C12-C15 aliphatic hydrocarbons (<2% aromatics) is not expected to meet the screening criteria for persistence.

C12-C15 aliphatic hydrocarbons (<2% aromatics) is an UVCB substance that contains constituents that have the potential to bioaccumulate. Thus, C12-C15 aliphatic hydrocarbons (<2% aromatics) meets the screening criteria for bioaccumulation.

Hydrocarbons, C11-14, n-alkanes, isoalkanes, cyclics (<2% aromatics) hydrocarbon fluid did not exhibit acute toxicity to fish, invertebrates, or algae at WAF up to 1,000 mg/L. Thus, C12-C15 aliphatic hydrocarbons (<2% aromatics) is not expected to meet the screening criteria for toxicity.

The overall conclusion is that C12-C15 aliphatic hydrocarbons (<2% aromatics) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Aspiration Toxicity Category 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If irritation occurs, get medical attention.

Skin Contact
Wash the contaminated area of with soap and water. Remove and isolate contaminated clothing. Launder contaminated clothing before reuse.

Inhalation
Move person to fresh air. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. Give artificial respiration if victim is not breathing.

Ingestion
Do not induce vomiting. Get medical attention immediately.

Notes to Physician
If ingested, material may be aspirated into the lungs and may cause chemical pneumonitis. Treat appropriately.

B. Fire Fighting Information

Extinguishing Media
Use water spray or fog, foam, dry chemical or carbon dioxide. Do not use straight streams of water.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapors, or spray Avoid contact with skin, eye, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Pick up with non-combustible absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Avoid breathing vapor or aerosol. Keep away from open flames, hot surfaces and sources of ignition. Provide sufficient ventilation in work area.

Storage
Keep container tightly closed and in a dry, well-ventilated place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for C12-C15 aliphatic hydrocarbons (<2% aromatics).

Engineering Controls
Use adequate ventilation to control air-borne concentrations.

Personal Protection Equipment
Respiratory Protection:
If workers are exposed to concentrations at a level that is not adequate to protect work health, they must use appropriate, certified respirators. The following type of respirator should be considered for this material: particulate, dust or mists. For high airborne concentrations, use an approved supplied-air respirator, operated in positive pressure mode.

Hand Protection:
Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection:
Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection:

Use chemical goggles.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

C12-C15 aliphatic hydrocarbons (<2% aromatics) is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

CONCAWE. PetroRisk: https://www.concawe.eu/reach/petrorisk/.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

CHLOROUS ACID, SODIUM SALT

This dossier on chlorous acid, sodium salt presents the most critical studies pertinent to the risk assessment of chlorous acid, sodium salt in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium chlorite

CAS RN: 7758-19-2

Molecular formula: $ClHO_2.Na$

Molecular weight: 90.44

Synonyms: Chlorous acid, sodium salt; sodium chlorite

SMILES: [O-]Cl=O.[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Chlorous Acid, Sodium Salt

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White solid, slightly hydroscopic crystals or flakes. Aqueous solutions are colorless to greenish yellow with a slight chlorine-like odor	2	ECHA
Melting Point	180 – 200°C; decomposes at 200°C	2	ECHA
Density	2.432 g/mL	1	ECHA
Vapor Pressure	1.1×10^{-7} Pa @ 25°C	1	ECHA

Property	Value	Klimisch score	Reference
Partition Coefficient (log K_{ow})	<-2.7	1	ECHA
Water Solubility	Very soluble (572 g/L @ 20°C)	1	ECHA
Oxidizing Properties	25.6% aq. solution – not an oxidizing liquid	1	ECHA

Chlorous acid, sodium salt in its dry form is a strong oxidizer.

Chlorous acid, sodium salt readily dissociates in aqueous solutions to the sodium (Na^+) and chlorite (ClO_2^-) ion. The chlorite (ClO_2^-) ion is in equilibrium with chlorous acid ($HClO_2$) in water. The chemical reaction is as follows:

$ClO_2^- + H^+ \rightleftharpoons HClO_2$

At pH values found in environmental media or physiological fluids, the chlorite ion will be the predominant form (pK_a of chlorous acid is 1.94).

Under acidic conditions, chlorous acid ($HClO_2$) will predominate and will disintegrate to chlorine dioxide (ClO_2). Chlorine dioxide (ClO_2) will degrade further to chlorite (ClO_2^-), and, ultimately, the chloride ion (Cl^-) is formed. The proportion of each oxy-chlorine species depends in part on the pH of the solution.

III. ENVIRONMENTAL FATE PROPERTIES

Chlorous acid, sodium salt readily dissociates in aqueous solutions to the sodium (Na^+) and chlorite (ClO_2^-) ion. The chlorite ion will ultimately degrade to chloride ions. Both sodium and chloride ions are ubiquitous in the environment. Biodegradation is not applicable to sodium chlorite. Neither sodium chlorite nor its dissociated ions are expected to adsorb to soil or sediment, or bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Chlorous acid, sodium salt (sodium chlorite) in solution is moderately-to-highly toxic by the oral route, but has low acute toxicity by the dermal route. It is corrosive the skin and eyes. It is not a skin sensitizer. The critical effect seen in rodents given repeated oral administration of sodium chlorite is hemolytic anemia. Sodium chlorite was not

mutagenic in a bacterial reverse mutation (Ames) test; however, chlorine dioxide (which breaks down to chlorite) was mutagenic in the mouse lymphoma assay in the absence and presence of metabolic activation. *In vivo* genotoxicity studies on sodium chlorite were generally negative. No reproductive toxicity was seen in male or female rats given sodium chlorite in drinking water. There was, however, an effect on post-natal development in pups from the first generation; the effect was not seen in the pups from the second generation. There was no developmental toxicity in pregnant female rabbits given sodium chlorite in drinking water.

B. Acute Toxicity

The oral LD_{50} in rats is 284 mg/kg (ECHA) [Kl. score = 1]. The oral LD_{50} in rats of a 31% aqueous solution of chlorous acid, sodium salt is 390 mg/kg (ECHA) [Kl. score = 2).

There are no acute inhalation toxicity studies.

The dermal LD_{50} in rabbits is 134 mg/kg (ECHA) [Kl. score = 1]. The dermal LD_{50} in rabbits of a 31% aqueous solution of chlorous acid, sodium salt is >2,000 mg/kg (ECHA) [Kl. score = 2).

C. Irritation

Application of 0.5 mL of undiluted chlorous acid, sodium salt to the skin of rabbits for 4 hours under occlusive conditions was corrosive (ECHA) [Kl. score = 2]. Application of 0.5 mL of a 34.5% solution of chlorous acid, sodium salt to the skin of rabbits for four hours under semi-occlusive conditions was essentially non-irritating (ECHA) [Kl. score = 1].

Instillation of 0.1 mL of a 31% aqueous solution of chlorous acid, sodium salt to the eyes of rabbits was severely irritating (ECHA) [Kl. score = 2].

D. Sensitization

Chlorous acid, sodium salt was not considered to be a skin sensitizer when tested in a mouse local lymph node assay (ECHA). [Kl. score = 1]

E. Repeated Dose Toxicity

<u>Oral</u>
Male and female Crj:CD(SD) rats were dosed by oral gavage with 0, 10, 25, or 80 mg/kg chlorous acid, sodium salt for 13 weeks. Five animals died during the study: one in the 25 mg/kg group and five in the 80 mg/kg group subsequent to blood sampling. The deaths in the 80 mg/kg group were likely treatment-related; the animals were anemic and blood sampling may have exacerbated this problem, contributing to their death. Clinical signs were noted in the 25 and 80 mg/kg animals, the most notable being

salivation. Body weights and feed consumption were similar across all groups. Hematological effects were noted in the 80 mg/kg animals. The group mean erythrocyte count was significantly lower (both sexes). In males, hematocrit and hemoglobin levels were significantly lower, and methemoglobin levels and neutrophils counts were significantly higher than controls. The reticulocyte count was increased, but was not statistically significant. Two of the 80 mg/kg rats that prematurely died had marked changes in these hematological parameters. Morphological changes were also seen in the blood smears of three 80 mg/kg females: these were polychromasia, poikilocytosis, macrocytosis, and neutrophilia. Lymphocyte counts were significantly lower than controls in the 80 mg/kg males, and was likely due to the increased neutrophil count. Where the primary red blood cell parameters (mean erythrocyte count, hemoglobin, and hematocrit) were affected, there were also associated changes in mean cell volume, mean cell hemoglobin, and mean cell hemoglobin concentration. In the 25 mg/kg animals (both sexes) and the 10 mg/kg males, statistical trends highlighted a dose-dependent downward trend for erythrocyte counts. Statistical significance was not confirmed by direct comparison with the control group, and group mean values were within background range. Urine volume was unusually high in four 80 mg/kg females, and urinary specific gravity was reduced. There were no histopathologic changes seen in the kidneys of these animals. Absolute and relative spleen weights were increased in the 80 mg/kg males. Absolute spleen weights were increased in the 10 and 80 mg/kg females; relative spleen weights were increased in the 25 and 80 mg/kg females. Relative adrenal weights were increased in the 80 mg/kg males. Absolute adrenal weights were increased in the 80 mg/kg females; relative adrenal weights were increased in the 25 and 80 mg/kg females. Histopathologic changes indicative of chronic irritation were seen in the stomachs of many of the 80 mg/kg animals and a few of the 25 mg/kg males. Extramedullary hematopoiesis was seen in the spleen of a few 80 mg/kg animals and one animal each in the lower two dose groups. The NOAEL for this study is 10 mg/kg-day (ECHA). [Kl. score = 1]

Male C/J and C57L/L mice were given in their drinking water 0, 0.75, 7.5, or 75 mg/L chlorous acid, sodium salt (0, 0.19, 1.9, or 19 mg/kg-day chlorite ion) for 30 days. There were slight signs of oxidative stress of red blood cells at the high-dose. Glucose-6-phosphate dehydrogenase (G6PD) activity and osmotic fragility were slightly increased. Erythrocytes with irregular shapes were also observed. It was suggested that the primary effect of chlorous acid, sodium salt was a disruption of the erythrocyte cell membrane. However, the glutathione level in the erythrocyte was not affected and there were no associated signs of hemolytic anemia, suggesting that the slight increase in G6PD activity acted as a sufficient compensatory mechanism to limit the oxidative stress. The NOAEL for this study is considered to be 7.5 mg/L chlorous acid, sodium salt or 1.9 mg/kg-day chlorite (Moore and Calabrese, 1980). [Kl. score = 2]

Male C57L/J mice were given chlorous acid, sodium salt in their drinking water for 30, 90, or 180 days. The doses were 0, 3, 15, or 75 mg/L expressed as chlorite ion. The average daily doses were estimated to be: 0, 0.74, 3.57, and 17.23 mg/kg-day for the

30-day period; 0, 0.64, 3.15, and 16.2 mg/kg-day for the 90-day period; and 0, 0.69, 3.71, and 17.11 mg/kg-day for the 180-day period. There were no significant changes in body weight gain, absolute or relative kidney weights, water consumption, or histopathologic changes in the kidney. The NOAELs for this study are: 17.23, 16.20, and 17.11 mg/kg-day for the 30-, 90-, and 180-day exposure periods, respectively (Connor et al., 1985). [Kl. score = 2]

Inhalation
No studies are available.

Dermal
No adequate studies are available.

F. Genotoxicity

In Vitro Studies

Table 2 lists the results of the *in vitro* genotoxicity studies on chlorous acid, sodium salt.

Table 2: *In vitro* Genotoxicity Studies on Chlorous Acid, Sodium Salt

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* TA97, TA102 strains)	-	-	4	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	+**	+**	2	ECHA

*+, positive; -, negative
**Test material: chlorine dioxide (chlorite is a breakdown product)

In Vivo Studies

Male and female CD-1 mice were given by oral gavage a single dose of 0, 0.2, 0.5, or 1 mg/day (0, 10, 25, or 59 mg/kg-day) chlorous acid, sodium salt. Chromosomal aberrations were not increased in bone marrow cells of treated mice compared to those in the controls (Meier et al., 1985; ECHA).

Male and female CD-1 mice were given by oral gavage 0, 0.2, 0.5, or 1 mg/day (0, 10, 25, or 59 mg/kg-day) chlorous acid, sodium salt for five consecutive days. There were no significant differences between treated and control mice in the frequency of micronuclei or chromosomal aberrations in bone marrow cells (Meier et al., 1985; ECHA).

Male ddY mice were given a single intraperitoneal injection of 0, 7.5, 15, 30, or 60 mg/kg chlorous acid, sodium salt. Micronucleated polychromatic erythrocytes were statistically significantly increased at all dose levels. The increase was dose-dependent, but the frequency of micronucleated polychromatic erythrocytes decreased at the highest dose level (Hiyashi et al., 1988; ECHA). [Kl. score = 2]

Male ddY mice were given a single intraperitoneal injection of 0 or 15 mg/kg chlorous acid, sodium salt for four consecutive days. The frequency of micronucleated polychromatic erythrocytes were similar between treated and control mice (Hiyashi et al., 1988; ECHA). [Kl. score = 2]

Male ddY mice were given a single oral dose of 0, 37.5, 75, 150, or 300 mg/kg chlorous acid, sodium salt. There was no significant increases in the frequency of micronucleated polychromatic erythrocytes in the bone marrow of the treated mice compared to the controls (Hiyashi et al., 1988; ECHA). [Kl. score = 2]

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

A two-generation reproductive toxicity study has been conducted on chlorous acid, sodium salt. Male and female SD rats were given in their drinking water 0, 35, 70, or 300 ppm chlorous acid, sodium salt. The average daily intakes are: 0, 4, 8, and 30 mg/kg-day for males ; and 0, 5, 10, and 39 mg/kg-day for females. The average daily intakes for chlorite are: 0, 2.9, 6, and 22 mg/kg-day for males; and 0, 4, 7.5, and 29 mg/kg-day for females. During lactation, the drinking water levels were reduced 50% to 17.5, 35, and 150 ppm chlorous acid, sodium salt. Water consumption was reduced in all treated groups. Body weights and feed consumption were reduced in the 70 and 300 ppm groups. There was no evidence of reproductive toxicity at any dose level. In the 300 ppm group, pup weights were reduced at birth and on PND 11 (-14%) compared to the controls. There was a decrease in the percent of the 300 ppm F_{2a} pups with eyes open on PND15 compared to the control group; this effects was not observed for the F_1 or F_{2b} pups. There was a small, but statistically significant, increase in the average time to preputial separation for the 70 and 300 ppm F_1 pups and in the vaginal opening for the 300 ppm F_1 pups. Similar changes were not observed for the F_2-generation pups. All of the high-dose animals exhibited mild methemoglobinemia. Thyroid levels were unaffected by treatment. There was a small decrease in the amplitude of auditory startle responses in the 70 and 300 ppm pups on PND 25; the toxicological significance of this effect is questionable. The NOAEL for reproductive toxicity is 300 ppm chlorous acid, sodium salt, the highest dose tested. The NOAEL for developmental toxicity is 35 ppm (4 and 5 mg/kg-day chlorous acid, sodium salt for males and females, respectively)

based on the increase in the average time to preputial separation in the ≥70 ppm F_1 pups. The NOAELs for hematological effects is 70 ppm (8 and 10 mg/kg-day chlorous acid, sodium salt for males and female, respectively). The NOAEL for neurotoxicity is 300 ppm (30 and 39 mg/kg-day chlorous acid, sodium salt for males and females, respectively) (ECHA) [Kl. = 2].

I. Developmental Toxicity

Pregnant New Zealand White rabbits were given 0, 200, 600, or 1,200 mg/L (0, 12.2, 36.6, or 58.8 mg/kg-day) chlorous acid, sodium salt in their drinking water during GD 7 to PND 19. The animals in the mid- and high-dose groups showed reduced water consumption, along with reduced feed consumption, production of fecal pellets, and body weight gain. There was no evidence of embryotoxicity or teratogenicity at any dose level. The NOAELs for maternal and developmental toxicity are 12.2 and 58.8 mg/kg-day, respectively (ECHA). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for chlorous acid, sodium salt follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL values from key toxicity studies on chlorous acid, sodium salt are listed below in Table 3.

Table 3: Lowest NOAEL Values from Key Toxicity Studies on Chlorous Acid, Sodium Salt by the Oral Route

Species/sex	Study Duration	mg/kg-day	Endpoint	Reference
Male/female rats	13 weeks	10	Clinical signs, stomach irritation	ECHA
Male pups	2-generation reproductive	4	- average time to preputial separation	ECHA
Male parental rats	2-generation reproductive	8	Hematological effects	ECHA

Species/sex	Study Duration	mg/kg-day	Endpoint	Reference
Female pregnant rabbits	Developmental (GD 6 to PND 17)	12.2	¯ Body weight gain, feed consumption	ECHA

The lowest NOAEL is 4 mg/kg-day based on increased average time to preputial separation in F_2 male pups from a two-generation reproductive toxicity study (ECHA). The NOAEL of 4 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Derivation of an Oral Reference Dose

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 4/(10 x 10 x 1 x 10 x 1) = 4/1000 = <u>0.004 mg/kg-day</u>

Derivation of a drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.004 x 70 x 0.1)/2 = <u>0.014 mg/L</u>

Australian Drinking Water Guidelines

The Australian drinking water guideline value for chlorite is 0.3 mg/L (ADWG, 2011).

The Australian drinking water guideline value for sodium is 180 mg/L based on aesthetics (ADWG, 2011).

B. Cancer

No carcinogenicity studies were found on chlorous acid, sodium salt. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Chlorous acid, sodium salt in solution does not exhibit the following physico-chemical properties:

· Explosivity
· Flammability
· Oxidizing Potential

[It should be noted that chlorous acid, sodium salt as a solid is a strong oxidizer.]

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Chlorous acid, sodium salt has a high acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 4 lists the results of acute aquatic toxicity studies conducted on chlorous acid, sodium salt.

Table 4: Acute Aquatic Toxicity Studies on Chlorous Acid, Sodium Salt

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LC_{50}	149	2	ECHA
Daphnia magna	48-h EC_{50}	<1	2	ECHA

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Peudokirchneriella subcapitata	96-h EC_{50}	1	1	ECHA

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for chlorous acid, sodium salt follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (149 mg/L), invertebrates (<1 mg/L), and plants (1 mg/L). On the basis that the data consists of short-term studies from three trophic levels, an assessment factor of 1,000 has been applied to the EC_{50} value of 1 mg/L for algae. The $PNEC_{aquatic}$ is 0.001 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Chlorous acid, sodium salt dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as chlorous acid, sodium salt. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of chlorous acid, sodium salt to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of chlorous acid, sodium salt is dominated by its water solubility. Sorption of chlorous acid, sodium salt should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{oc} and K_{ow} parameters do not readily apply to inorganics, such as chlorous acid, sodium salt. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, chlorous acid, sodium salt is not expected to significantly adsorb

to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Chlorous acid, sodium salt is an inorganic salt that dissociates completely in water to sodium (Na^+) and chlorite (ClO_2^-) ions. Chlorite will ultimately degrade to chloride (Cl^-) ions. Biodegradation is not applicable to these inorganic ions. For the purposes of this PBT assessment, the persistent criteria is not considered applicable to this inorganic salt.

As an inorganic compound, neither chlorous acid, sodium salt nor its dissociated ions are expected to accumulate. Thus, chlorous acid, sodium salt does not meet the criteria for bioaccumulation.

There are no chronic toxicity studies on chlorous acid, sodium salt. The acute $E(L)C_{50}$ values for chlorous acid, sodium salt are $\leq$1 mg/L in invertebrates and algae. Thus, chlorous acid, sodium salt meets the criteria for toxicity.

The overall conclusion is that chlorous acid, sodium salt is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification (Chlorous acid, sodium salt solutions)

Acute Toxicity Category 3 [Oral]
Skin Corrosive Category 1B
STOT RE Category 2 [Target organ: blood]
Aquatic Acute Category 1
Aquatic Chronic Category 3
AUH031: Contact with acids liberates toxic gas (non-GHS hazard statement)

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
Remove and isolate contaminated clothing. Rinse skin immediately with water for at least 15 min. Get medical attention immediately.

Inhalation
Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion
Rinse mouth with water and then drink plenty of water. Get medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

Notes to Physician
Chlorine dioxide vapors are emitted when this product contacts acids or chlorine. If these vapors are inhaled, monitor patient closely for delayed development of pulmonary edema which may occur up to 48-72 hours post-inhalation Following ingestion, neutralization and use of activated charcoal is not indicated (OxyChem, 2015).

B. Fire Fighting Information

Extinguishing Media
Use dry chemical, carbon dioxide, water spray or fog, or foam.

Specific Exposure Hazards
Dried material can ignite upon contact with combustibles. This product may represent an explosion hazard if it contacts acids, chlorine, or organic materials. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: chlorine and sodium oxides.

Special Protective Equipment for Firefighters
Structural firefighter's protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible. Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Wear positive pressure self-contained breathing apparatus (SCBA). Move containers from fire area if it can be done without risk.

C. Accidental Release Measures

Personal Precautions
Ventilate enclosed areas. Do not walk through spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapors, or spray. Do not get in eyes, on skin, or on clothing.

Environmental Precautions
Prevent entry into waterways, sewers, basements or confined areas.

Steps to be Taken if Material is Released or Spilled
As an immediate precautionary measure, isolate spill or leak area for at least 50 meters in all directions. Keep unauthorized personnel away. Remove all sources of ignition. Absorb or cover with dry earth, sand, or other non-combustible material and transfer to containers. Dike to collect large liquid spills. Every attempt should be made to avoid mixing spilled material with other chemicals or debris when cleaning up. Dried material can ignite upon contact with combustibles. Dispose immediately.

D. Storage And Handling

General Handling
Do not get in eyes, on skin, or on clothing. Do not ingest or taste. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours, or spray. Use caution when combining with water. DO NOT add water to corrosive liquid, ALWAYS add corrosive liquid to water while stirring to prevent release of heat, steam, and fumes. This product becomes a fire hazard if allowed to dry. Remove and wash contaminated clothing to avoid fire.

Storage
Keep contain tightly closed. Store in a cool, dry, well-ventilated place. Keep from direct sunlight. Avoid exposure to sunlight or ultraviolet light. Keep separated from acids, reducing agents, combustible material, oxidizing agents, hypochlorite, organic solvents and compounds, garbage, dirt, organic materials, household products, chemicals, soap products, paint products, vinegar, oils, pine oil, dirty rags, sulfur-containing rubber, or any other foreign matter.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for chlorous acid, sodium salt.

Engineering Controls
Good general ventilation should be used. Localized ventilation should be used where vapours, mist, or aerosols may be generated.

Personal Protection Equipment
Respiratory Protection:
Wear an approved acid gas respirator with dust/mist pre-filters if any exposure to dust of mist is possible.

Hand Protection:
Wear appropriate chemical-resistant gloves.

Skin Protection:
Wear protective clothing to minimize skin contact.

Eye protection:
Wear chemical splash goggles and face shield.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium chlorite (dry)
UN1496 (SODIUM CHLORITE)

Class: 5.1
Packing Group: II

Environmentally Hazardous Substance

Sodium chlorite (liquid)
UN1908 (CHLORITE SOLUTION)
Class: 8
Packing Group: II
Contains Sodium chlorite

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Connor, P.M., Moore, G.S., Calabrese, E.J., and Howe, G.R. (1985). The renal effects of sodium chlorite in the drinking water of C57L/J male mice. J. Environ. Pathol. Oncol. 6: 263-260.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Hiyashi, M., Kishi, M., Sofuni, T., and Ishidate, M. (1988). Micronucleus tests in mice on 39 food additives and eight miscellaneous chemicals. Fd. Chem. Toxicol. 26: 487-500.

Meier, J.R, Bull, R.J., Stober, J.A., and Cimino, M.C. (1985). Evaluation of chemicals used for drinking water disinfection for production of chromosomal damage and sperm-head abnormalities. Environ. Mutagen. 7: 201-211.

Moore, G.S., and Calabrese, E.J. (1980). The effects of chlorine dioxide and sodium chlorite on erythrocytes of A/J and C57LJ mice. J. Environ. Pathol. Toxicol. 4: 513-524.

Oxychem (2015). OxyChem Sodium Chlorite Handbook. Available at: http://www.oxy.com/OurBusinesses/Chemicals/Products/Documents/SodiumChlorite/Sodium%20Chlorite%20Handbook.pdf

CHOLINE CHLORIDE

This dossier on choline chloride (CAS RN 67-48-1) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on choline chloride (OECD, 2004), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-hydroxy-N,N,N-trimethylethanaminium chloride

CAS RN: 67-48-1

Molecular formula: $C_5H_{14}NO.Cl$

Molecular weight: 139.6 g/mol

Synonyms: Choline chloride; 2-hydroxy-N,N,N-trimethylethanaminium chloride; trimethyl(2-hydroxyethyl)ammonium chloride; cholinium chloride; 2-hydroxyethyl(trimethyl)azanium chloride

SMILES: C[N+](C)(C)CCO.[Cl-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Choline Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	White crystalline solid*	2	OECD (2004)
Melting Point	~ 200°C @ 101.3 kPa	1	ECHA
Boiling Point	Decomposition at 305°C @ 101.3 kPa prior to boiling	2	ECHA
Density	70% aq. solution: 1110 kg/m^3@ 20°C	4	OECD (2004)
Partition Coefficient (log K_{ow})	75% aq. solution: -3.77 @ 25°C	1	ECHA
Vapour Pressure	2287.2 Pa @ 25°C (QSAR)	2	ECHA
Water Solubility	Powder containing 50% choline chloride: 650 g/L (temperature unknown	4	OECD (2004)
Auto flammability	330°C	2	ECHA

Property	Value	Klimisch score	Reference
Viscosity	75% aq. solution: 26.2 mPa.s @ 20°C; 14.1 mPa.s @ 40°C	1	ECHA
Henry's Law Constant	2.06 x 10-11 Pa.m^3/mol @ 25 °C (estimated using HENRYWIN v3.10)	-	OECD (2004)

*Choline chloride is a white crystalline solid; it is marketed as an aqueous solution (70-75% w/w in water), which is colourless with an amine-like odour.

Choline chloride is a quaternary amine salt that will dissociate in water into choline ($C_5H_{14}NO^+$) ions and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

A. Partitioning

Choline chloride is highly water soluble and non-volatile. When released to water under typical environmental conditions, the quaternary ammonium salt dissociates to release a positively charged choline ion and a negatively charged chloride ion (OECD, 2004). It is unlikely to partition to the atmosphere based on its low volatility (OECD, 2004).

B. Biodegradation

Choline chloride is readily biodegradable (93% within 14 days) in a MITI-I test (MITI, 1992; OECD, 2004). In another MITI-I test, biodegradation was $\geq$60%, indicating ready biodegradation (Tunkel *et al.*, 2000; OECD, 2004). A $BOD_5/ThOD_5$ ratio of 75% was obtained in a BOD_5 test performed according to DIN 38409 part 43 (BASF AG, 1984; OECD, 2004).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

No experimental data are available for choline. Choline is a quaternary ammonium compound (QAC); these compounds are not included in the training set for the K_{oc} estimation of the QSAR model KOCWIN v. 2.00 in EPISuite™ (USEPA, 2016), and therefore outside the program's prediction domain. A K_{oc} value of 2.3 had been estimated using the older QSAR model PCKOCWIN v. 1.66 (OECD, 2004), indicating a low potential for soil adsorption.

Results from Mackay Level I modelling indicate that choline chloride will be distributed completely into water (OECD, 2004).

D. Bioaccumulation

No measured data on bioaccumulation of choline chloride is available. An experimental log K_{ow} is -3.77, which indicates a low potential to accumulate in organisms (OECD, 2004). Bioaccumulation is not expected in aquatic organisms.

E. Summary

Choline chloride is readily biodegradable. Distribution modelling using Mackay Level 1 shows choline to be distributed completely into water. Choline chloride will not adsorb on soil and sediments. It is not expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Choline is a vitamin-like essential nutrient. It has low acute toxicity by the oral route and is slightly irritating to the skin and eyes. Repeated high intake of choline in humans has been reported to cause a slight hypotensive effect. No adverse effects (including tumours) were seen in rats given choline in the diet for 72 weeks. Choline is not genotoxic. High dietary doses of choline to pregnant mice resulted in developmental toxicity (but no teratogenic effects) at levels that were maternally toxic.

NICNAS has assessed fumaric acid in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Metabolism

Choline is a vitamin-like essential nutrient. Although the body can synthesise choline in small amounts, it is insufficient to maintain health and must be consumed in the diet. Choline is required for the synthesis of phospholipids in cell membranes, methyl group metabolism and acetylcholine synthesis (neurotransmitter) (Zeisel and Blusztajn, 1994).

Dietary choline is taken up into the body by transporter proteins present in the cells lining the small intestine (IOM, 2000). In the small intestine, prior to uptake into the small intestinal cells, some choline is metabolised by bacteria to betaine and methylamines (Zeisel et al., 1980). Dietary choline can be present as free choline or in esterified forms (i.e., phosphocholine, glycerophosphocholine, sphingomyelin, and phosphatidylcholine) (Zeisel and Blusztain, 1994). Free choline is formed from these esterified choline compounds by pancreatic enzymes.

Choline is involved in a number of biochemical pathways in eukaryotic and prokaryotic cells. It is a precursor for acetylcholine (a neurotransmitter); phospholipids (structural integrity and signaling roles for cell membranes); and a major source for methyl groups (IOM, 2000).

C. Acute Toxicity

<u>Oral</u>

The oral LD_{50} values of choline in rats are approximately 3,500 and 5,500 mg/kg (ECHA) [Kl. scores = 2].

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 110-17-8%2C+

Inhalation

No acute inhalation or dermal toxicity studies are available.

D. Irritation

Skin

Application of a 70% aqueous solution to the skin of rabbits for 20 hours under occlusive conditions resulted in ambiguous skin irritation (BASF AG, 1963a; OECD, 2004) [Kl. score = 2].

Eye

Slight eye irritation was seen in the eyes of rabbits after instillation of a 70% aqueous solution of choline chloride; no effects were seen 24 hours after exposure (BASF AG, 1963b; OECD, 2004) [Kl. score = 2].

E. Sensitisation

No data are available in animals. In a Human Repeated Insult Patch Test (HRIPT), there was no evidence of dermal sensitisation in 200 subjects given 0.5% (w/v) aqueous solution of choline chloride during the induction phase and 0.2% (w/v) aqueous solution during the challenge phase (Colgate-Palmolive, 2003; OECD, 2004).

F. Repeated Dose Toxicity

Oral

A 72-week feeding study was conducted to investigate the impact of choline chloride on the liver tumour promoting activity of phenobarbital and DDT in diethylnitroamine-initiated Fischer 344 rats. Animals received approximately 500 mg/kg/day choline chloride. Following the end of the exposure period, the animals were kept on the same untreated diet as the control group until study termination at week 103. Histopathology was limited to the liver and organs that developed gross abnormalities. There were no significant differences between treated and control animals on survival rates, body weights, and relative liver weights. There were no increased number of neoplastic liver nodules, hepatocellular carcinomas, lung tumours, leukemia or other tumours between treated and control animals. The NOAEL for choline chloride in this study is 500 mg/kg-day (Shivapurkar *et al.*, 1986) [Kl. score = 3].

In humans, oral administration of 10,000 mg/day choline chloride in a pilot study treating a small number of patients with Alzheimer's disease resulted in a slight hypotensive effect (Boyd *et al.*, 1977). This dose was regarded as a LOAEL by the U.S. Institute of Medicine (IOM) Standing Committee on the Scientific Evaluation of Dietary Reference Intake (2000).

Inhalation

No adequate or reliable studies are available.

Dermal

No adequate or reliable studies are available.

G. Genotoxicity

In Vitro Studies

Choline chloride was not mutagenic to bacteria in reverse mutation assays (Haworth *et al.*, 1983, Litton Bionetics, 1977).

A small, but statistically significant, and dose-related increase in chromosomal aberrations was reported in Chinese Hamster Ovary (CHO) cells at doses of 50 and 500 µg/mL choline chloride in the absence of S9 only (Bloom *et al.*, 1982). No higher concentrations were examined. These results could not be confirmed in two studies using CHO cells at concentrations of choline chloride up to 5,000 µg/mL (Galloway *et al.*,1985).

In sister chromatid exchange (SCE) assays, ambiguous results were obtained in two parallel studies (at two different laboratories) in CHO cells at concentrations up to 50 and 5,000 µg/mL choline chloride, respectively. Cytotoxicity was observed at 5,000 µg/mL. In laboratory 2, the increase in SCEs, which was sporadic and not dose-related, that was observed with metabolic activation was not reproduced in laboratory 1. Laboratory 1 showed a weak positive at the top dose without metabolic activation, but a comparison with laboratory 2 was not possible due to the insufficient number of cells analysed (Bloom *et al.*, 1982; Galloway *et al.*, 1985).

Choline chloride was negative in a gene conversion assay with *Saccharomyces cerevisiae* strain D4 in the presence or absence of metabolic activation (Litton Bionetics, 1977; OECD, 2004).

In Vivo Studies

No studies are available.

H. Carcinogenicity

Oral

No studies are available.

Inhalation

No studies are available.

I. Reproductive Toxicity

No reliable studies have been conducted that address female fertility or reproductive toxicity by a relevant route of exposure.

J. Developmental Toxicity

Oral

Pregnant female mice were given in their feed 0, 1, 2.5, 5, or 10% choline chloride (0 or approximately 1,250, 4,160, 10,800, or 20,000 mg/kg choline chloride) on gestational days 1 to 18. Maternal body weight gain was reduced in all treated groups except for the 1,250

mg/kg group. Maternal weight gain of dams with embryonic/foetal absorptions showed no net weight gain at >4,160 mg/kg, but there was net weight loss in the 20,000 mg/kg group. All foetuses were resorbed in the 20,000 mg/kg group. Embryonic/foetal lethality of 35% and 69% were seen in the 4,160 and 10,800 mg/kg groups, respectively. No resorptions occurred in the 1,250 mg/kg group. Developmental toxicity was seen at >4,160 mg/kg group. There were no statistically significant increases in malformations in any dose group. The NOAEL for maternal and developmental toxicity is 1,250 mg/kg/day (BASF AG, 1966; OECD, 2004) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for choline chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The Standing Committee on the Scientific Evaluation of Dietary Reference Intakes selected hypotension as the critical effect from the study by Boyd *et al.* (1977) when deriving a Tolerable Upper Intake Level. Boyd *et al.* (1977) reported a LOAEL of 10,000 mg/day choline chloride (7,500 mg/day choline). An uncertainty factor of 2 was chosen because of the limited data regarding hypotension and the inter-individual variation in response to cholinergic effects. Thus, the value for the Tolerable Upper Intake Level or repeated exposure of adults to choline is 3,500 mg/day choline.

Note that the Australian National Health and Medical Research Council (2014) concluded that there are no data to suggest that there is increased susceptibility to choline during pregnancy or lactation; thus, the upper level of intake choline is the same for women during pregnancy or lactation as it is for adults (3,500 mg/day choline).

Oral Reference Dose (oral RfD)

An oral RfD for choline is derived as follows: the LOAEL of 7,500 mg/day from the Boyd *et al.* (1977) study is divided by an uncertainty factor of 2 to obtain a value of 3,500 mg choline/day or 50 mg choline/kg/day for a 70 kg person.

Oral RfD = 50 mg/kg/day [choline]

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (50 x 70 x 0.1)/2 = 175 mg/L [choline]

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2021).

B. Cancer

There are no carcinogenicity studies on choline chloride. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Choline chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Choline chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on choline chloride.

Table 2: Acute Aquatic Toxicity Studies on Choline Chloride

Test Species	Endpoint	Results (mg/L)[1]	Klimisch score	Reference
Oryzias latipes	96-hour LC_{50}	>100 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)
Leuciscus idus	96-hour LC_{50}	>10,000*	2	OECD (2004); ECHA
Daphnia magna	48-hour EC_{50}	349 (nominal and measured)	2	MOE Japan (1999b); OECD (2004)
Daphnia magna	48-hour EC_{50}	>500*	2	OECD (2004)
Pseudokirchneriella subcapitata	72-hour EC_{50}	>1,000 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)

*78% aqueous solution of choline chloride

Chronic Studies

In a 21-day *Daphnia magna* reproduction test, the nominal and measured NOEC was reported to be 30.2 mg/L (MOE Japan, 1999d) [Kl. score = 1].

The NOEC from a 72-hr algae *Pseudokirchneriella subcapitata* study is 30.2 mg/L (MOE Japan, 1999c; OECD, 2004) [Kl. score = 1].

C. Terrestrial Toxicity

No data is available.

Choline is present in all plant and animal cells, mostly in the form of phospholipids (phosphotidylcholine or lecithin, lysophosphatidylcholine, choline plasmalogens and sphingomyelin), which are essential components of membranes (IOM, 2000).

D. Calculation of PNEC

The PNEC calculations for choline chloride follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (>100 mg/L), invertebrates (349 mg/L) and algae (>1,000 mg/L). Results from chronic studies are available for invertebrates (21-day NOEC = 30.2 mg/L) and algae (72-hour NOEC = 32 mg/L). On the basis that the data consists of chronic studies on two trophic level (albeit not on the species with the lowest $E(L)C_{50}$), an assessment factor of 100 has been applied to the lowest reported NOEC of 30 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 0.3 mg/L (0.22 mg/L for choline).

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.15 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1{,}000 \times PNEC_{water}$
$= (0.844/1280) \times 1{,}000 \times 0.22$
$= 0.15$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1{,}000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.092/1{,}000 \times 2400]$
$= 0.844\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 2.3 x 0.04

= 0.092 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ for choline is 0.007 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1{,}000 \times PNEC_{water}$

= (0.05/1500) x 1,000 x 0.22

= 0.007 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 2.3 x 0.02

= 0.05 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Choline chloride is readily biodegradable and thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -3.77, choline chloride does not meet the criteria for bioaccumulation.

The NOEC values from chronic toxicity studies on choline chloride are >0.1 mg/L. Thus, choline chloride does not meet the criteria for toxicity.

The overall conclusion is that choline chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, nitrogen oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Choline chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Australian National Health and Medical Research Council (2014). Nutrient Reference Values for Australia and New Zealand: Choline. Accessed at: https://www.nrv.gov.au/nutrients/choline

BASF AG (1963a). Toxicity of choline chloride 70 % in water; skin irritation after exposure to choline chloride. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1963b). Toxicity of choline chloride 70% in water; eye irritation. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1966). Study on teratogenic effects of choline chloride in the mouse after oral application. Department of Toxicology. Unpublished results. Study No. XIV/156. 14 Oct. 1966.

BASF AG (1984). Department of Product Safety. Laboratory of Ecology. Pruefbericht ueber eine Untersuchung auf biologische Abbaubarkeit im BSB5-Test - Cholinchlorid (German). Test No. 01606. 16 Feb. 1984.BASF AG (2004b). Department of Product Safety. Unpublished calculation. Mackay Level I V2.11. 29 Jun. 2004.

Bloom A., Galloway, S., Nakamura, F.T., Teteviri, A., Armstrong, M., Lavappa, K.L., Duk, S., and Ahmed, M.A. (1982). Comparison of results for SCE and chromosome aberrations for eleven compounds tested in two laboratories by standardized methods. Environ. Mutagen. 4: 397.

Boyd, W.D., Graham-White, J., Blackwood, G., Glen, I., and McQueen, J. (1977). Clinical effects of choline in Alzheimer senile dementia. Lancet 2: 711.

Colgate-Palmolive (2003). Study No. DCR-200-137-TKL. TKL Research Inc. Paramus, NJ, USA. In: SCCNFP. Scientific Committee on Cosmetic Products and Non-Food Products. Choline Chloride. SCCNFP/0672/03. 9 Dec. 2003.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Galloway, S.M., Bloom, A..D, Resnick, M., Margolin, B.H., Nakamura, F., Archer, P., and Zeiger, E, (1985). Development of a standard protocol for in vitro cytogenetic testing with Chinese hamster ovary cells: Comparison of results for 22 compounds in two laboratories. Environ. Mutagen. 7: 1-51.

Haworth, S., Lawlor, T., Mortelmans, K., Speck, W., and Zeiger, E. (1983). Salmonella mutagenicity test results for 250 chemicals. Environ. Mutagenesis Suppl. 1: 3-142.

Institute of Medicine [IOM] (2000). Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. . Standing Committee on the Scientific Evaluation of Dietary Reference Intake, Institute of Medicine, National Academy Press, Washington D.C.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Litton Bionetics (1977). Mutagenic evaluation of compound FDA75-69.000067-48-1. choline chloride. FCC. Report No. PB-266 891. Mar. 1977.

MITI (1992). Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan. Edited by Chemicals Inspection & Testing Institute Japan, published by Japan Chemical Industry Ecology-Toxicology & Information Center. October 1992.

MOE Japan (1999a). Ministry of Environment. Acute toxicity study of choline chloride on the Orange killifish *Oryzias latipes*. Unpublished study. No. 1998-16.

MOE Japan (1999b). Ministry of Environment. Acute toxicity study of choline chloride on *Daphnia magna*. Unpublished study. No. 1998-14.

MOE Japan (1999c). Ministry of Environment. Acute toxicity study of choline chloride on the freshwater alga *Pseudokirchnerialla subcapitata*. Unpublished study. No. 1998-13.

MOE Japan (1999d). Ministry of Environment. Chronic toxicity study of choline chloride on the freshwater invertebrate *Daphnia magna*. Unpublished study. No. 1998-15.

OECD (2004). SIDS Initial Assessment Report for Choline chloride (CAS No. 67-48-1), UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/67481.pdf

Shivapurkar, N., Hoover, K.L., and Poirier, L.A. (1986). Effect of methionine and choline on liver tumor promotion by phenobarbital and DDT in diethylnitrosamine-initiated rats. Carcinogenesis 7: 547- 550.

Tunkel J., Howard, P.H., Boethling, R.S., Sitteler, W., and Loonen, H. (2000). Predicting ready biodegradability in the Japanese Ministry of international trade and industry test. Environ. Toxicol. Chem. 19: 2478-2485.

U.S. Environmental Protection Agency [EPA] (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Zeisel, S.H., Story, D.C., Wurtman, R.J., and Brunengraber, H. (1980). Uptake of free choline by isolated perfused rat liver. Proc. Natl. Acad. Sci. USA 77(8): 4417-4419.

Zeisel, S.H., and Blusztajn, J.K. (1994). Choline and human nutrition. Ann. Rev. Nutr. 14: 269-296.

CINNAMALDEHYDE

This dossier on cinnamaldehyde presents the most critical studies pertinent to the risk assessment of cinnamaldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2E)-3-phenylprop-2-enal

CAS RN: 104-55-2

Molecular formula: C_9H_8O

Molecular weight: 132.16

Synonyms: Cinnamaldehyde; (2E)-3-phenylprop-2-enal; 3-phenylacrylaldehyde; cinnamal; (E)-cinnamaldehyde; 3-phenylpropenal; cinnamic aldehyde; phenylacrolein; cinnamylaldehyde; 3-phenyl-2-propenal; trans-cinnamaldehyde; (E)-3-phenylpropenal; (E)-3-phenyl-2-propenal; 3-phenylacrolein; 3-phenyl-2-propenaldehyde; 3-phenyl-2-propen-1-al; acrolein, 3-phenyl-; 2-propenal, 3-phenyl-; 2-propenal, 3-phenyl-, (2E)-

SMILES: C1=CC=C(C=C1)C=CC=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Cinnamaldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless liquid	1	ECHA
Melting point	-18°C	1	ECHA
Boiling point	>250°C	1	ECHA
Density	1.0414 g/cm^3 @ 20°C	1	ECHA
Vapor pressure	0.0289 mm Hg @ 25°C	1	ECHA
Partition coefficient (log K_{ow})	2.107 @ 25°C	1	ECHA

Property	Value	Klimisch score	Reference
Water solubility	2110 mg/L @ 22°C	1	ECHA
Flash point	105°C	1	ECHA
Auto flammability	Not auto-flammable.	1	ECHA
Viscosity	22.12 mPa s @ 20°C 18 mPa s @ 40°C	1	ECHA
Henry's Law Constant	0.162 Pa m^3/mol	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is expected to biodegrade and not expected to bioaccumulate to any significant extent. Detailed available information is provided below.

B. Biodegradation

Cinnamaldehyde is readily biodegradable. In an OECD 301B test, degradation of cinnamaldehyde was 89% after 7 days, 94% after 14 days, and 100% after 28 days, indicating ready biodegradation (ECHA) [Kl. score = 2]. In an OECD 301D test, biodegradation was 24.98% after 5 days. The BOD_5 value was 0.635 mg O_2/mg (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for cinnamaldehyde. Using KOCWIN in EPISUITE™ (EPA, 2018), the estimated K_{oc} value from log K_{ow} of 2.107 is 55.82 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 36.82 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on cinnamaldehyde. Cinnamaldehyde is not expected to bioaccumulate based on a log K_{ow} of 2.107 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Cinnamaldehyde is of relatively low acute toxicity. It is an irritant to skim and eyes and is considered a sensitizer per the guinea pig maximization test. Oral repeat dose studies suggest

relatively low toxicity with no data on inhalation or dermal exposures. The substance is not mutagenic in *in vitro* and *in vivo* testing and is not carcinogenic.

B. Acute Toxicity

The oral LD_{50} in rats is 2,220 mg/kg (ECHA) [Kl. score = 2].

No acute inhalation studies are available.

The dermal LD_{50} in rats is >2,000 mg/kg (ECHA) [Kl. score = 2].

C. Irritation

Application of cinnamaldehyde to the skin of rabbits for 4 hours under semi-occlusive conditions was considered a slight-to-moderate irritant. Cinnamaldehyde was severely irritating when applied for 24 hours under occlusive conditions (ECHA) [Kl. score = 2].

Cinnamaldehyde was considered to be a severe skin irritant when tested in a human patch test. Cinnamaldehyde, at doses of 0.02, 0.1%, and 0.8% in ethanol, was applied to the skin over a six-week period (ECHA).

Instillation of 0.1 mL cinnamaldehyde to the eyes of rabbits was considering irritating. The mean of the 24, 48, and 72 hours scores were: 1.00 for corneal opacity, 0.00 for iridial lesions, 2.00 for conjunctival redness, and 1.22 for chemosis. All effects were resolved by Day 14 of the observation period (ECHA) Kl. score = 1).

D. Sensitization

Cinnamaldehyde was considered a skin sensitizer when tested in a guinea pig maximization test (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

Male and female F344 rats were given in their diet 0, 4,100, 8,200, 16,500, or 33,000 ppm cinnamaldehyde (microcapsulated) for three months in a study conducted by the National Toxicology Program. The average daily intake was 0, 275, 625, 1,300, and 4,000 mg/kg-day for males, and 0, 300, 570, 1,090, and 3,100 mg/kg-day for females. There was no mortality during the study. Mean body weights were reduced in the ≥16,500 ppm animals as a result of decreased feed consumption from unpalatability of the dosed feed. There was a non-significant increase in serum bile acid concentration at all dose levels suggesting an effect on the liver, but there were no corresponding histopathologic effects. An increase in lesions of the forestomach mucosa was seen in the ≥8,200 ppm animals and included squamous epithelial hyperplasia. There was also chronic active inflammation in the 33,000 ppm males and the ≥16,500 ppm females. The NOAEL was considered to be 4,100 ppm, which corresponds to 275 and 300 mg/kg-day in males and females, respectively (Hooth et al., 2004; ECHA) [Kl. score = 1].

Male and female rats were fed in their diet 0, 1,000, 2,100, or 4,100 ppm cinnamaldehyde for 12 weeks. The average daily intake was 0, 50, 100, or 200 mg/kg-day. There were no significantly differences between treated and control animals in urine sugar and albumin, blood hemoglobin levels, growth, food intake, or other physiological criteria. The NOAEL for this study is 4,100 ppm for males and females, which corresponds to 200 mg/kg-day (ECHA) [Kl. score = 2].

Male and female F344 rats were given in their diet 0, 1,000, 2,100, or 4,100 ppm cinnamaldehyde (microcapsulated) for two years in a study conducted by the National Toxicology Program. The average daily intake was 0, 50, 100, or 200 mg/kg-day. The survival of the 4,100 ppm males was greater than the controls. The mean body weights of the 4,100 ppm animals were generally less he controls throughout the study. Feed consumption of the $\geq$2,100 ppm males and the 4,100 ppm females was less than the controls at the beginning and end of the study. There were no non-neoplastic lesions that were considered to be treatment-related. The NOAEL for this study is 4,100 ppm for males and females, which corresponds to 200 mg/kg-day (Hooth et al., 2004; ECHA) [Kl. score = 1].

Male and female B6C3F_1 mice were given in their diet 0, 1,000, 2,100, or 4,100 ppm cinnamaldehyde (microcapsulated) for two years in a study conducted by the National Toxicology Program. The average daily intake was 0, 125, 270, or 540 (males) and 570 (females) mg/kg-day. Mean body weights of the $\geq$2,100 ppm animals were generally less than the controls throughout the study. There were no non-neoplastic lesions that were considered to be treatment-related. Incidences of minimal olfactory epithelial pigmentation was significantly increased in the 4,100 ppm males and the $\geq$2,100 ppm females. The NOAEL for this study is 1,000 ppm in males and females, which corresponds to 125 mg/kg-day, based on reduced body weights at 270 mg/kg-day (Hooth et al., 2004; ECHA) [Kl. score = 1].

Inhalation
No studies are available.

Dermal
No adequately reported studies are available.

F. Genotoxicity

In Vitro Studies

Cinnamaldehyde was not mutagenic to *S. typhimurium* strains TA 1535, TA 1537, TA 97, TA 98, or TA 100 in the absence or presence of metabolic activation (ECHA) [Kl. score = 2].

In Vivo Studies

Male and female B6C3F_1 mice were administered in their feed 0, 4,100, 8,200, 16,500, or 33,000 ppm cinnamaldehyde (microcapsulated) for three months in a study conducted by the National Toxicology Program. The average daily intake was 650, 1,320, 2,550, and 5,475 mg/kg-day for males, and 0, 625, 1,380, 2,680, and 5,200 mg/kg-day for females. There were no increases in the frequency of micronucleated normochromatic erythrocytes in the peripheral blood in the treated animals compared to the controls (ECHA) [Kl. score = 2].

G. Carcinogenicity

Male and female F344 rats were administered in their diet 0, 1,000, 2,100, or 4,100 ppm cinnamaldehyde (microcapsulated) for two years in a study conducted by the National Toxicology Program. The average daily intake was 0, 50, 100, or 200 mg/kg-day. The tumor incidences were similar between the treated and control animals (Hooth et al., 2004; ECHA) [Kl. score = 1]

Male and female B6C3F_1 mice were administered in their diet 0, 1,000, 2,100, or 4,100 ppm cinnamaldehyde (microcapsulated) for two years in a study by the National Toxicology Program. The average daily intake was 0, 125, 270, or 540 (males) and 570 (females) mg/kg-day. The tumor incidences were similar between the treated and control animals (Hooth et al., 2004; ECHA) [Kl. score = 1]

H. Reproductive Toxicity

No adequate studies are available.

I. Developmental Toxicity

Pregnant female CD-1 mice were dosed by oral gavage with 0 or 1,200 mg/kg cinnamaldehyde on gestational days 6 to 13. The dams were allowed to deliver, and the pups were weaned up to postnatal day 3. There was no effect on maternal survival or body weight development and all 34 litters were viable. The number of lifeborns per litter, the survival and birthweight of pups and their weight gain was not affected by treatment. The NOAEL for maternal and developmental toxicity is 1,200 mg/kg-day (ECHA) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for cinnamaldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>
Rat and mouse two-year feeding studies have been conducted on cinnamaldehyde (Hooth et al., 2004; ECHA). The lowest NOAEL from these studies is 1,000 ppm in the diet for male and female mice (which corresponds to 125 mg/kg-day), based on reduced body weights at 270 mg/kg-day. The NOAEL of 125 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10

UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 125/(10 x 10 x 1 x 1 x 1) = 125/100 = 1.0 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (1.25 x 70 x 0.1)/2 = 4 mg/L

B. Cancer

Cinnamaldehyde was not carcinogenic to rats or mice when given in the diet for two years. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Cinnamaldehyde does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute aquatic toxicity studies are available for a wide variety of aquatic organisms. 96 hour LC 50 values for fish are greater then 3.5 mg/L. EC50 values invertebrates and algae ranged from 3.21 to 16.09 milligrams per liter. Detailed information from these studies is provided below.

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies on cinnamaldehyde.

Table 2: Acute Aquatic Toxicity Studies on Cinnamaldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Brachydanio rerio	96-hr LC_{50}	4.15	1	ECHA
Poecilia reticulata	96-hr LC_{50}	>3.5	1	ECHA
Daphnia magna	48-hr EC_{50}	3.21	1	ECHA
Desmodesmus subspicatus	72-hr EC_{50}	31.6	1	ECHA
Chlorella vulgaris	72-hr EC_{50}	16.09	1	ECHA

Chronic Studies
In an OECD 210 chronic fish toxicity study, the 28-day LOEC to *Oryzias latipes* was 66.08 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for cinnamaldehyde follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (4.15 mg/L), *Daphnia* (3.21 mg/L), and algae (16.09 mg/L). Results from a chronic fish study are available, with a LOEC of 66.08 mg/L. The NOEC from this study can be calculate as the LOEC/2 or 33 mg/L. On the basis that the data consists of short-term results from three trophic levels and a long-term study, an assessment factor of 100 has been applied to the lowest reported NOEC or $E(L)C_{50}$ value of 4.15 mg/L for fish. The $PNEC_{water}$ is 0.04 mg/L.

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.02 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.74/1500) \times 1000 \times 0.04$
$= 0.02$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
= 36.82 x 0.02
= 0.74

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for cinnamaldehyde based on the molecular connectivity index (MCI) is 36.82 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Cinnamaldehyde is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 2.107, cinnamaldehyde does not meet the screening criteria for bioaccumulation.

The NOEC from a chronic fish study is >0.1 mg/L. The acute $E(L)C_{50}$ values for cinnamaldehyde are >1 mg/L. Thus, cinnamaldehyde does not meet the criteria for toxicity.

The overall conclusion is that cinnamaldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Skin Irritant Category 2
Eye Irritant Category 2
Skin Sensitizer Category 1
Aquatic Acute Toxicity Category 2
STOT SE3

B. Labelling

Warning!

According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye irritation, is harmful to aquatic life with long lasting effects, is harmful in contact with skin, causes skin irritation and may cause an allergic skin reaction.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils, or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop. SKIN: IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Skin Contact

IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Inhalation

IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

Ingestion

DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious, do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport the victim to a hospital. (NTP, 1992)

Notes to Physician

Symptoms of exposure to this compound may include inflammation and erosion of gastrointestinal mucosa. The vapor or mist causes irritation of the eyes, mucous membranes and upper respiratory tract. ACUTE/CHRONIC HAZARDS: This chemical may be harmful by inhalation, ingestion or skin absorption. It may cause irritation of the skin, eyes, upper respiratory tract, and mucous membranes. When heated to decomposition it may emit toxic fumes of carbon monoxide and carbon dioxide.

Medical Conditions Aggravated by Exposure
Irritation properties of the substance may aggravate asthma and/or other respiratory conditions.

Emergency Personnel Protection
Personal protective equipment must be used in accordance with known hazards of the substance.

B. Fire Fighting Information

Extinguishing Media
This chemical is combustible. Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher.

Specific Exposure Hazards
May ignite after a delay period in contact with NaOH.

Special Protective Equipment for Firefighters
Use respiratory protection equipment as deemed necessary by hazards associated with the substance.

C. Accidental Release Measures

Personal Precautions
Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet. Remove clothing immediately if substance gets inside. Then wash thoroughly and put on clean clothing.

Environmental Precautions
Do not release to discharge into open drains or waterways.

Steps to be Taken if Material is Released or Spilled
If you spill this chemical, FIRST REMOVE ALL SOURCES OF IGNITION. Then, use absorbent paper to pick up all liquid spill material. Contaminated clothing and absorbent paper should be sealed in a vapor-tight plastic bag for eventual disposal. Solvent wash all contaminated surfaces with 60-70% ethanol followed by washing with a soap and water solution. Do not reenter the contaminated area until the Safety Officer (or other responsible person) has verified that the area has been properly cleaned.

Wastewater from contaminant suppression, cleaning of protective clothing/equipment, or contaminated sites should be contained and evaluated for subject chemical or decomposition

product concentrations. Concentrations shall be lower than applicable environmental discharge or disposal criteria. Alternatively, pretreatment and/or discharge to a POTW is acceptable only after review by the governing authority. Due consideration shall be given to remediation worker exposure (inhalation, dermal and ingestion) as well as fate during treatment, transfer and disposal.

Do not contaminate water by cleaning of equipment or disposal of wastes

D. Storage and Handling

General Handling
Do not use, pour, spill or store near heat or open flame.

Other Handling Precautions
Observe label precautions. Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.

Storage
STORAGE PRECAUTIONS: You should keep this material in a tightly closed container under an inert atmosphere, and store it at refrigerated temperatures. (NTP, 1992)

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure limit for cinnamaldehyde.

Engineering Controls
Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment
Respiratory Protection:
Where the neat test chemical is weighed and diluted, wear a NIOSH-approved half face respirator equipped with an organic vapor/acid gas cartridge (specific for organic vapors, HCl, acid gas and SO2) with a dust/mist filter. (NTP, 1992)

Hand Protection:
Chemical resistant gloves.

Skin Protection:
For agricultural use requirements, PPE required for early entry to treated areas that is permitted under applicable Worker Protection Standards and that involves contact with anything that has been treated, such as plants, soil, water, is: Coveralls, waterproof gloves, shoes plus socks.

Eye protection:
Protective eyewear shall be worn at all times.

Other Precautions:
None other specific precautions are stipulated.

F. Transport Information

Cinnamaldehyde is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

CITRIC ACID

This dossier on citric acid presents the most critical studies pertinent to the risk assessment of citric acid in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on citric acid (OECD 2001a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Hydroxy-1,2,3-propanetricarboxylic acid

CAS RN: 77-92-9

Molecular formula: $C_6H_8O_7$

Molecular weight: 192.122

Synonyms: citric acid; 1,2,3-propanetricarboxylic acid, 2-hydroxy-; 2-hydroxy-1,2,3-propanetricarboxylic acid

SMILES: C(C(=O)O)C(CC(=O)O)(C(=O)O)O

Citric acid is an ubiquitous natural substance that is an intermediate in the basic physiological tricarboxylic acid (TCA) cycle in every eukaryote cell.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Citric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystalline solid; odourless.	2	ECHA
Melting Point	153°C	2	ECHA
Boiling Point	Not available; decomposition	-	ECHA
Density	1.67 @ 20°C	2	ECHA
Vapor Pressure	2.21 x 10^{-6} Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-1.61 to -1.80	2	ECHA
Water Solubility	Very soluble	4	ECHA
Flash Point	345°C	4	ECHA
Auto flammability	1010°C	4	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Citric acid is readily biodegradable. It is not expected to bioaccumulate. Due to its high water solubility, citric acid is unlikely to adsorb to soil or sediment.

B. Biodegradation

Citric acid can be considered readily biodegradable based on the results of the ready and inherent aerobic biodegradation studies listed in Table 2.

Table 2: Biodegradation Studies on Citric Acid (OECD 2001a,b)

Test System	Results*	Notes	Klimisch Score
Modified Sturm	97% (CO_2 evolution); 100% (DOC removal)	Readily biodegradable; exposure period not stated	2
Closed Bottle Test	BOD_{30}/COD Ratio = 90%	Readily biodegradable	2
BOD_5/COD Ratio	BOD_5 = 526 mg; COD = 728 mg; BOD_5/COD Ratio = 0.72	Readily biodegradable; concentration of test substance and activated sludge not stated	2
BOD_1/ThOD Ratio	BOD_1/ThOD Ratio = 13%	-	2
BOD_{20}/ThOD Ratio	BOD_{20}/COD Ratio = 98%	Readily biodegradable; initial test substance concentration 720 mg/L	2
Zahn-Wallen Test	85%, 1 day (DOC removal)	Inherently biodegradable	2
Zahn-Wallen Test	98%, 7 days (DOC removal)	Inherently biodegradable	
Coupled Units Test	93% (COD removal)	Ultimately biodegradable; exposure period not stated.	2

C. Environmental Distribution

Absorption/desorption

No experimental data are available for citric acid. Using KOCWIN program in EPISuite™ (EPA, 2016), the estimated K_{oc} value from the K_{ow} value of -1.08 is 0.3617 L/kg.

D. Bioaccumulation

The log K_{ow} for citric acid is -1.61 to -1.80. Thus, citric acid is not expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Citric acid exhibits low toxicity by the oral and dermal routes. It is an eye irritant, but slightly to non-irritating to the skin. No adequate studies were found to evaluate the sensitization potential of citric acid. Minimal toxicity and no carcinogenic effects were observed in rats given oral doses of citric acid for up to two years. Citric acid was not mutagenic to bacteria, but *in vitro* studies using human

lymphocytes showed genotoxic effects. *In vivo* genotoxicity studies were negative. There were no reproductive or developmental effects in rats given oral doses of citric acid.

B. Acute Toxicity

The acute oral LD_{50} in male rats was reported to be 11,700 mg/kg (ECHA) [Kl. score = 2]. The acute oral LD_{50} values in mice are 5,400 and 5,790 mg/kg (ECHA) [Kl. score = 2]. The acute dermal LD_{50} value in rats is >2,000 mg/kg (ECHA) [Kl. score = 1].

C. Irritation

Application of 0.5 g citric acid powder to the skin of rabbits for 4 hours under semi-occlusive conditions was slightly irritating. The mean of the 24, 48, and 72-hour scores were: 0.3 for erythema and 0.0 for edema (ECHA) [Kl. score = 1]. Application of a 50% aqueous solution of citric acid to the skin of rabbits for 4 hours under occlusive conditions was non-irritating (ECHA) [Kl. score = 2].

Instillation of a 30% aqueous solution of citric acid into the eyes of rabbits produced well defined to moderate conjunctival irritation that did not fully resolve after the 14-day observation period. A 10% solution was associated with weak to moderate conjunctival effects, which resolved after 7 days (ECHA) [Kl. score = 2].

D. Sensitization

No adequate studies were found to evaluate the sensitization potential of citric acid.

E. Repeated Dose Toxicity

Oral
Male rats were given 0, 1.2, 2.4, or 4.8% citric acid in their feed for 6 weeks. The daily intakes were reported to be 1,150, 2,260, or 4,670 mg/kg-day. The high-dose animals had mild blood and urine parameter changes and slight degeneration of the thymus gland and spleen. The NOAEL is 2.4% in the diet or 2,260 mg/kg-day (OECD, 2001a,b). [Kl. score = 4]

Rats were given 3% or 5% citric acid in their diet for two years. The estimated daily intakes were 1,200 and 2,000 mg/kg-day, respectively. A slight decrease in growth was reported in the 2% group, but no tissue abnormalities in the major organs. The NOAEL is 1,200 mg/kg-day (OECD, 2001a,b). [Kl. score = 4]

Inhalation
No studies are available.

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

Citric acid was not mutagenic in bacterial reverse mutation assays with strains of *S. typhimurium* or *E. coli* with and without metabolic activation (OECD, 2001a,b; ECHA). [Kl. score = 2]

Peripheral human lymphocytes were treated with 50 to 3,000 µg/ml citric acid. A statistically significant dose-dependent increase in the micronuclei was observed. In another set of studies by

the same laboratory, there was a statistically significant and dose-related increase in the number of cells with aberrations, including sister chromatid unions. The study authors reported that the pH of the medium was unchanged (ECHA). [Kl. score = 2]

In Vivo Studies

Citric acid was not mutagenic in a dominant lethal assay when male rats were given either a single oral dose of citric acid (1.2 to 120 mg/kg) or a single oral dose on five consecutive days (300 to 3,500 mg/kg) (OECD 2001a,b) [Kl. score = 2]. There were no increases in chromosomal aberrations in the bone marrow of rats given either a single oral dose of citric acid (1.2 to 120 mg/kg) or a single oral dose on five consecutive days (300 to 3,500 mg/kg) (ECHA) [Kl. score = 2].

G. Carcinogenicity

Oral

There was no evidence of carcinogenicity in rats given 3% or 5% citric acid in feed (1,200 or 2,000 mg/kg/day, respectively) for two years (OECD, 2001a,b). [Kl. score = 4]

H. Reproductive Toxicity

In a non-standard repeat dose dietary study (duration and frequency not specified), 5% citric acid in feed did not affect either the number of young born to mice or rats or their subsequent survival up to the point of weaning (ECHA). [Kl. score = 4]

I. Developmental Toxicity

Pregnant female rats were dosed by oral gavage with 0, 2.95, 13.7, 63.6, or 295 mg/kg citric acid on GD 6-15. No maternal or developmental effects were noted. The NOAEL for maternal and developmental toxicity is 295 mg/kg-day, the highest dose tested (OECD, 2001a,b; ECHA).
[Kl. score = 2]

Pregnant female rats were dosed by oral gavage with 0, 2.41, 11.2, 52, or 241 mg/kg citric acid on GD 6-15. No maternal or developmental effects were noted. The NOAEL for maternal and developmental toxicity is 241 mg/kg-day, the highest dose tested (OECD, 2001a,b; ECHA).
[Kl. score = 2]

Pregnant female rabbits were dosed by oral gavage with 0, 4.25, 19.75, 91.70, or 425 mg/kg citric acid on GD 6-18. No maternal or developmental effects were noted. The NOAEL for maternal and developmental toxicity is 425 mg/kg-day, the highest dose tested (OECD, 2001a,b; ECHA).
[Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for citric acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

In a two-year dietary study, the only effect seen in rats fed either 3 or 5% citric acid (approx. 1,200 or 2,000 mg/kg-day) was a slight decrease in growth in the 5% dose group. In the absence of statistical analysis of the body weight gain data, a conservative approach was taken, and the 5% dose group

was considered an LOAEL. The NOAEL of 3% citric acid in the diet (1,200 mg/kg-day) will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)
Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1

Oral RfD = 1,200/(10 x 10 x 1 x 1 x 1) = 1,200/100 = 12 mg/kg-day

Drinking water guidance value
Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
- Human weight = 70 kg (ADWG, 2011)
- Proportion of water consumed = 10% (ADWG, 2011)
- Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (12 x 70 x 0.1)/2 = 42 mg/L

B. Cancer

Citric acid was not carcinogenic to rats in a chronic dietary study. Thus, no cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Citric acid does not exhibit the following physico-chemical properties:
- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Citric acid is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

The 48-hour LC_{50} values in *Leuciscus idus melanotus* (golden orfe) from two separate laboratories were 440 mg/L and 760 mg/L (ECHA) [Kl. scores = 2]. The 96-hour LC_{50} in *Lepomis macrochirus* (fathead minnow) is >100 mg/L (ECHA) [Kl. score = 2).

The 24-hour EC_{50} in *Daphnia* is 85 mg/L in un-neutralized test solution and 1,535 mg/L in a neutralized solution (OECD, 2001a,b; ECHA). [Kl. score = 2]

The 8-day toxicity threshold value (EC_0) in *Scenedesmus quadricauda* is 640 mg/L (ECHA; OECD, 2001a,b). [Kl. score = 2]

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for citric acid follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for only fish (440 mg/L) and *Daphnia* (1,535 mg/L, neutralized). On the basis that the data consist of short-term results from two trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 440 mg/L for fish. The $PNEC_{water}$ is 0.44 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.277 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.807/1280) \times 1000 \times 0.44$
$= 0.277$

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{soilid}]$
$= 0.8 + [0.2 \times 0.014/1000 \times 2400]$
$= 0.807$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
= 0.3617 x 0.04
= 0.014

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for citric acid is estimated to be 0.3617 L/kg.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.002 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
= (0.007/1500) x 1000 x 0.44
= 0.002
Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
= 0.3617 x 0.02
= 0.007

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for citric acid is estimated to be 0.3617 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009, ECHA, 2008).

Citric acid is readily biodegradable; thus, it does not meet the screening criteria for persistence.

The log K_{ow} values for citric acid are -1.61 to -1.80. Thus, citric acid does not meet the screening criteria for bioaccumulation.

There are no adequate chronic aquatic toxicity studies on citric acid. The acute $E(L)C_{50}$ values for citric acid are >1 mg/L in fish and invertebrates. Thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that citric acid is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

The information in this section is for a citric acid solution.

A. Classification

Eye Irritant Category 2

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
No data are available.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilt
Pick up with absorbent material. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling
No special measures necessarily provided product is used correctly.

Other Handling Precautions
Avoid eye and skin contact.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for citric acid.

Engineering Controls
None

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Citric acid is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2001a). IUCLID Data Set for Citric acid (CAS No. 77-92-9), UNEP Publications.

OECD (2001b). Screening Information Dataset (SIDS) Initial Assessment Report for Citric acid (CAS No. 77-92-9), UNEP Publications).

U.S. Environmental Protection Agency [EPA] (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

1-PROPANAMINIUM, 3-AMINO-N-(CARBOXYMETHYL)-N,N,-DIMETHYL-N-COCO ACYL DERIVS., HYDROXIDES, INNER SALTS
[COCOAMIDOPROPYL BETAINE]

This dossier on 1-propanaminium, 2-amino-N-(carboxymethyl)-N,N-dimethyl-N-cocoalkyl [cocoamidopropyl betaine] presents the most critical studies pertinent to the risk assessment of cocoamidopropyl betaine in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on alkylamidopropyl betaines, which includes cocoamidopropyl betaine (OECD, 2006; OECD, 2007), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-,N-coco acyl derivs., hydroxides, inner salts

CAS RN: 61789-40-0

Molecular formula (mean)* [1]: $C_{12.8}H_{39.8}N_2O_3$ [OECD, 2007]

Molecular weight (mean)* [1]: ca. 355 g/mol [OECD, 2007]

Synonyms: 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-,N-coco acyl derivs., hydroxides, inner salts; 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl,N-coco acyl derivs., hydroxides, inner salts; 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-,N-coco acyl derivs., inner salts; cocoamidopropyl betaine; cocoamido propyl betaine; cocoamidopropylbetaine; N-cocamidopropyl-dimethylglycine; coco amide propylbetaine; acetobetain, dimethyl-C12-18-acylamidopropyl-; (N-cocoamidopropyl)-N,N-dimethylglycin, hydroxide, inner salts

SMILES: O=C(NCCCN(CC(=O)O)(C)C)CCCCCCCCCCC for C12 fatty acid

[1] *The calculation of the molecular formula and weight is based on the typical alkyl chain length distribution:
C8: 7% (Caprylamidopropyl betaine)
C10: 6% (Capramidopropyl betaine)
C12: 51% (Lauramidopropyl betaine)
C14: 18% (Tetradecylamidopropyl betaine, Myristamidopropyl betaine)
C16: 8% (Palmitamidopropyl betaine)
C18: 10% (Stearamidopropyl betaine)

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Cocoamidopropyl Betaine

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	ECHA
Melting point	283°C (calculated for C12 fatty acid; QSAR)	2	OECD, 2007; ECHA
Boiling point	651°C for C12 fatty acid (calculated; QSAR)	2	OECD, 2007; ECHA
Density	1.05 – 1.07 g/cm^3	2	OECD, 2007
Vapor pressure	0 PA @ 25°C (calculated; QSAR)	2	OECD, 2007
Partition coefficient (log K_{ow})	-1.28 to -3.63 @ 25°C*	4	OECD, 2007
Water solubility	1.62-8,769 mg/L @ 25^{0}C (calc.) $\geq$10 g/L @ 25°C (aq. soln, measured)	2	OECD, 2007
Flash point	>230°C	4	HERA, 2005
Auto flammability	Not auto-flammable	1	OECD, 2007

*log Kow (C8) = -1.28; log Kow (C10) = -0.30; log Kow (C12) = 0.69; log Kow (C14) = 1.67; log Kow (C16) = 2.65; log Kow (C18) = 3.63.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Cocamidopropyl betaine is readily biodegradable; has a low potential to bioaccumulation; and is expected to have low-to-moderate adsorption to soil and sediment.

B. Biodegradation

Cocamidopropyl betaine is readily biodegradable. In an OECD 301 D test, degradation was 84% after 30 days (ECHA) [Kl. score = 2]. In an OECD 301 E test, degradation was 90% and 100% after 14 and 28 days, respectively (ECHA) [Kl. score = 2]. In an OECD 301 B test, degradation was 84% an 99% after 7 and 28 days, respectively (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental studies are available on cocamidopropyl betaine. Using KOCWIN v2.00, the K_{oc} value calculated by the MCI method for cocamidopropyl betaine with a C12 fatty acid side chain is 648 L/kg (ECHA) [Kl. score = 2].

D. Bioaccumulation

No experimental studies are available on cocamidopropyl betaine. Using the QSAR model BCFBAF v3.01, the bioaccumulation factor (BCF) of cocamidopropyl betaine with a C12 fatty acid chain was estimated to be 70.8 L/kg (ECHA). Thus, the bioaccumulation potential of cocamidopropyl betaine is low (ECHA) [Kl. score = 2].

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of cocamidopropyl betaine is low-to-moderate by the oral and dermal routes. An aqueous solution of 30% cocamidopropyl betaine is not irritating to the skin. The potential for eye irritation is dependent on the concentration of cocamidopropyl betaine: a 5-10% solution is slight-to-moderately irritating, while a 30% solution is severely irritating. Cocamidopropyl betaine has shown some skin sensitizing responses in both guinea pigs and humans; the response is thought to be due to impurities. Repeated dose toxicity studies in rats by the oral route have shown that cocamidopropyl betaine is irritating to the gastrointestinal tract, with no indication of any systemic effects up to 300 mg/kg-day. It is not genotoxic; and there was no indication of developmental toxicity in rats given cocamidopropyl betaine by the oral route.

B. Acute Toxicity

The oral LD_{50} values for cocoamidopropyl betaine are >1,500 mg/kg [Kl. scores = 1].

No acute inhalation studies are available on cocoamidopropyl betaine.

The dermal LD_{50} value in rats for cocoamidopropyl betaine is >600 mg/kg (OECD, 2007) [Kl. score = 1].

C. Irritation

Application of 0.5 g. of a 30-35% aqueous solution of cocoamidopropyl betaine to the skin of rabbits under semi-occlusive conditions were not irritating (OECD, 2007) [Kl. scores = 1].

There are several eye irritation studies conducted on cocamidopropyl betaine in rabbits. A 5-10% solution of cocamidopropyl betaine produced mild to moderate irritation to the eyes of rabbits, which were reversible; solutions containing 15% were irritating to highly irritating; and a 30% aqueous solution was irritating with irreversible damage (OECD, 2006; OECD, 2007 [Kl. scores = 1 and 2].

D. Sensitization

Two independent guinea pig maximization tests have been conducted on cocoamidopropyl betaine (OECD, 2006). There was no sensitization response in one test [Kl. score = 2], and the second test gave ambiguous results [Kl. score = 2]. The purity of the cocoamidopropyl betaine was not reported.

The sensitizing potential of cocoamidopropyl betaine in humans is low. Commercial cocoamidopropyl betaine may, however, contain impurities identified as sensitizers (amidoamine and/or 3-dimethylaminopropylamine) which may explain positive results in human patch tests. There is no evidence for a photosensitizing potential. In a guinea pig adjuvant study with less stringent test conditions, cocoamidopropyl betaine was not a skin sensitizer (OECD, 2006) [Kl. score = 2]. A modified Draize sensitization test with guinea pigs also showed no sensitization response with cocoamidopropyl betaine (OECD, 2006; OECD, 2007) [Kl. score = 2].

A few cases of sensitization in humans have been reported from the use of personal cleansing products containing cocoamidopropyl betaine. It is thought that these cases may have been due to impurities of cocoamidopropyl betaine, such as amidoamine and DMPA, that could be present in the formulations (OECD, 2006). Nonetheless, cocamidopropyl betaine can be considered to be a potentially weak skin sensitizer.

E. Repeated Dose Toxicity

Oral

Male and female SD rats were dosed by oral gavage with 0, 250, 500 or 1,000 mg/kg of a 30% aqueous solution of cocoamidopropyl betaine, 5 days/week for 28 days. The only treatment-related findings were forestomach lesions at the highest dose level, probably as a result of the irritant effect of the test substance. The NOAEL for systemic toxicity in this study is 1,000 mg/kg-day, which corresponds to 300 mg cocoamidopropyl betaine/kg-day (OECD, 2006; OECD, 2007) [Kl. score = 2].

Male and female SD rats were dosed by oral gavage with 0, 250, 500 or 1,000 mg/kg of a 30% aqueous solution of cocoamidopropyl betaine, 5 days/week for 90 days. The only treatment-related findings were forestomach lesions at the 500 and 1,000 mg/kg dose levels, probably as a result of the irritant effect of the test substance. The NOAEL for systemic toxicity in this study is 1,000 mg/kg- day, which corresponds to 300 mg cocoamidopropyl betaine/kg-day (OECD, 2006; OECD, 2007) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results from in vitro genotoxicity studies on cocoamidopropyl betaine are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Cocoamidopropyl Betaine

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	OECD, 2007
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	OECD, 2007
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	OECD, 2007
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	4	OECD, 2007

*+, positive; -, negative

In Vivo Studies

Male and female OF1 mice were given intraperitoneal injections of 0, 20, or 200 mg/kg of a 27% solution of cocoamidopropyl betaine on two consecutive days. The frequency of micronucleated erythrocytes were similar in the bone marrow cells of the treated mice compared to that in the control mice (OECD, 2006; OECD, 2007) [Kl. score = 2].

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Pregnant female CD rats were dosed by oral gavage with 0, 330, 990, or 3,300 mg/kg of a 28.9% aqueous solution of cocoamidopropyl betaine on GD 5 to 19. The dams in the $\geq$990 mg/kg dose groups had reduced body weights and stomach ulcers. Embryotoxic effects (increased numbers of resorptions, decreased number of viable fetuses, decreased fetal body weight) were observed only in the 3,300 mg/kg dose group. The NOAEL for maternal toxicity was 330 mg/kg-day (corresponding to 95 mg cocoamidopropyl betaine/kg-day). The NOAEL for developmental toxicity was 990 mg/kg-day, which corresponds to 286 mg cocoamidopropyl betaine/kg-day (OECD, 2006; OECD, 2007) [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for cocamidopropyl betaine follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

In a 90-day rat oral study, there were no treatment-related effects associated with systemic toxicity at 300 mg/kg-day cocoamidopropyl betaine, the highest dose tested. The NOAEL of 300 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 300/(10 x 10 x 1 x 3 x 1) = 300/300 = 1 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

There are no carcinogenicity studies on cocoamidopropyl betaine. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Cocoamidopropyl betaine does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The acute and chronic toxicity of cocamidopropyl betaine is of moderate concern to aquatic life.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on cocamidopropyl betaine.

Table 3: Acute Aquatic Toxicity Studies on Cocamidopropyl Betaine

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-hr LC_{50}	2	2	ECHA
Daphnia magna	48-hr EC_{50}	6.4	2	ECHA
Desmodesmus subspicatus	72-hr EC_{50}	48 (growth)	4	ECHA

Chronic Studies
The 28-day NOEC for cocamidopropyl betaine in *Oncorhynchus mykiss* is 0.16 mg/L (ECHA) [Kl. score = 4].

The 21-day NOEC for cocamidopropyl betaine in a Daphnia reproduction test is 0.9 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for cocamidopropyl betaine follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (2 mg/L), invertebrates (6.4 mg/L), and algae (48 mg/L). The NOEC values from chronic studies are available for fish (0.16 mg/L) and invertebrates (0.9 mg/L). On the basis that the data consists of acute studies from three trophic levels and chronic studies from two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC value of 0.16 mg/L for fish. The $PNEC_{aquatic}$ is 0.0032 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.033 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (13.24/1280) \times 1000 \times 0.0032$
$= 0.033$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 25.92/1000 \times 2400]$
$= 13.24$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 648 \times 0.04$
$= 25.92$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for cocamidopropyl betaine with a C12 fatty acid side chain calculated from KOCWIN v2.0 using the MCI method is 648 L/kg (ECHA).
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.028 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (12.96/1500) \times 1000 \times 0.0032$
$= 0.028$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
$= 648 \times 0.02$
$= 12.96$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for cocamidopropyl betaine with a C12 fatty acid side chain calculated from KOCWIN v2.0 using the MCI method is 648 L/kg (ECHA)F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Cocamidopropyl betaine is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on calculate BCF values of 70.8 L/kg, cocamidopropyl betaine does not meet the screening criteria for bioaccumulation.

The chronic toxicity data on cocamidopropyl betaine is >0.1 mg/L. The acute $E(L)C_{50}$ values for cocamidopropyl betaine in fish, invertebrates, and algae are >1 mg/L. Thus, cocamidopropyl betaine does not meet the screening criteria for toxicity.

The overall conclusion is that cocamidopropyl betaine is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

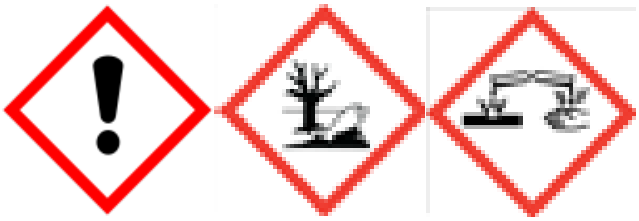
A. Classification

Skin Irritant Category 2
Eye Irritant Category 2
Skin Sensitizer Category 1
Aquatic Chronic Toxicity Category 3

B. Labelling

Warning
According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye irritation, is harmful to aquatic life with long lasting effects, causes skin irritation and may cause an allergic skin reaction.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention if symptoms persist.

Ingestion
Rinse mouth with water. If material has been swallowed, give small quantities of water to drink. Do not induce vomiting. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, alcohol-resistant foam, carbon dioxide. Do not use water jet as an extinguisher, as this will spread the fire.

Specific Exposure Hazards
Fine dust clouds may form explosive mixtures with air. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include: carbon dioxide, carbon monoxide, nitrogen oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Keep unnecessary personnel away. Keep people away from an upwind of spill or leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation.

Environmental Precautions
Prevent entry into waterways, sewers, basements or confined areas.

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste. Large spills: dike the spilled material.

D. Storage and Handling

General Handling
Avoid contact with eyes. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling.

Storage
Store in original tightly closed container. Store away from incompatible materials (strong oxidizing agents, peroxides, phenol).

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for cocamidopropyl betaine.

Engineering Controls
Ensure adequate ventilation, especially in confined areas.

Personal Protection Equipment
Respiratory Protection:
In case of insufficient ventilation, wear suitable respiratory equipment.

Hand Protection:
For prolonged or repeated skin contact use suitable protective gloves.

Skin Protection:
Wear suitable protective clothing.

Eye protection:
Wear safety glasses with side shields (or goggles).

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible. Routinely wash work clothing and protective equipment to remove contaminants.

F. Transport Information

Cocamidopropyl betaine is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2006). SIDS Initial Assessment Report on Alkylamidopropyl betaines (Cocoamidopropyl betaine, Lauramidopropyl betain). Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=F588B2B9-9862-45E3-804B-1E3113BC85EC.

OECD (2007). SIDS Dossier for 1-propanaminium, 3-amino-N-(carboxymethyl)-N,N-dimethyl-,N-coco acyl derivs., hydroxides, inner salts (CAS No. 61789-40-0). Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=F588B2B9-9862-45E3-804B-1E3113BC85EC.

ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER

This dossier on acrylamide/sodium acrylate copolymer presents the most critical studies pertinent to the risk assessment of acrylamide/sodium acrylate copolymer in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: 2-Propenoic acid, sodium salt, polymer with 2-propenamide

CAS RN: 25085-02-3

Molecular formula: $(C_3H_5NO.C_3H_4O_2.NA)_x$-

Molecular weight: No information is available. Based on the type and intended use of the copolymer, the molecular weight would likely range from 100,000 to >3,000,000 daltons (Hamilton *et al.*, 1997).

Synonyms: Acrylamide/sodium acrylate copolymer; 2-propenamide, polymer with 2-propenoic acid, sodium salt; 2-propenoic acid, sodium salt, polymer with 2-propenamide; 2-Propenamide-sodium 2 propenoate copolymer; sodium acrylate acrylamide polymer; sodium acrylate-acrylamide copolymer

SMILES: Not applicable.

II. PHYSICAL AND CHEMICAL PROPERTIES

No information is available.

III. ENVIRONMENTAL FATE PROPERTIES

No studies are available. The acrylamide/sodium acrylate copolymer is not expected to be readily biodegradable. The physico-chemical properties of the copolymer would preclude it from undergoing significant biodegradation (Guiney *et al.*, 1997). Biodegradation is limited due to the very high molecular weight and the low water solubility of the copolymer. The copolymer will likely bind tightly to organic matter found within soils and sediments (Guiney *et al.*, 1997). The copolymer is not expected to bioaccumulate because of its poor water solubility and high molecular weight.

IV. HUMAN HEALTH HAZARD ASSESSMENT

No studies are available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

NICNAS has assessed acrylamide/sodium acrylate copolymer in an IMAP Tier 1 assessment and considers it a “polymer identified as a low concern to human health by application of expert validated rules[1].”

[1] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-i-human-health-assessments#cas-A_25085-02-3

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Acrylamide/sodium acrylate copolymer does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

No studies are available. Acrylamide/sodium acrylate copolymer is expected to be a low concern for toxicity to aquatic organisms (Guiney *et al.*, 1997). Due to its poor solubility and high molecular weight, it is not expected to be bioavailable. It does not contain any reactive functional groups (*i.e.*, cationic groups).

A. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Acrylamide/sodium acrylate copolymer is not readily biodegradable; thus it meets the screening criteria for persistence.

Acrylamide/sodium acrylate copolymer is expected to have a very high molecular weight and poor water solubility. It is not expected to be bioavailable. Thus this copolymer does not meet the criteria for bioaccumulation.

There are no aquatic toxicity studies on acrylamide/sodium acrylate copolymer. It is expected to have low concern for aquatic toxicity because of its very high molecular weight and poor water solubility. Thus the copolymer does not meet the criteria for toxicity.

The overall conclusion is that acrylamide/sodium acrylate copolymer is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Burning produces harmful and toxic fumes. Heat from fire may melt, decompose polymer, and generate flammable vapors. Combustion products may include: Nitrogen oxides, carbon monoxide, carbon dioxide, and unburned hydrocarbons (smoke). Dust can accumulate static charges which can cause an incendiary electrical discharge. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source, is a potential dust explosion hazard.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Potential combustible dust hazard. Avoid generating dust. Creates dangerous slipping hazard on any hard smooth surface.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage and Handling

General Handling
Avoid dust accumulation in enclosed space. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion

hazard. Electrostatic charge may build up during handling. Equipment, container and metal containers should be grounded and bonded.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Use adequate ventilation to avoid excessive dust accumulation. Store away from excessive heat and away from strong oxidizing agents. Take measures to prevent the build up of electrostatic charge.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure limit for acrylamide/sodium acrylate copolymer.

Engineering Controls

Use in a well-ventilated area. Avoid creating dust. Take precautionary measures against static charge.

Personal Protection Equipment

Respiratory Protection:

Not normally needed; however, if significant exposures are possible, then the following respirator is recommended: Dust/mist respirator.

Hand Protection:

Normal work gloves

Skin Protection:

Normal work coveralls

Eye protection:

Wear safety glasses or goggles to protect against exposure.

Other Precautions:

Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Acrylamide/sodium acrylate copolymer is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Guiney, P. D., McLaughlin, J. E., Hamilton, J. D., and Reinert, K. H. (1997). Dispersion Polymers. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs (Hamilton, J.D. and Sutcliffe, R. eds.), pp. 147-165, Van Nostrand Reinhold.

Hamilton, J. D., Vasconcellos, S. R., and Keener, R. L. (1997). Introduction. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs (Hamilton, J.D. and Sutcliffe, R. eds.), pp. 3-15, Van Nostrand Reinhold.

Klimisch, H. J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol Pharmacol. 25:1-5.

CROTONALDEHYDE

This dossier on crotonaldehyde presents the most critical studies pertinent to the risk assessment of crotonaldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2E)-but-2-enal

CAS RN: 4170-30-3

Molecular formula: C4H6O

Molecular weight: 70.091

Synonyms: Crotonaldehyde, Crotoinic aldehyde, β-Methacrolein, β-Methyl acrolein, 2-butenal, Propylene aldehyde

SMILES: C/C=C/C=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Crotonaldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Water-white to straw-colored liquid with a pungent odor.	2	ECHA
Melting point	-76°C	2	ECHA
Boiling point	102.2°C	2	ECHA
Density	0.852 g/cm^3 @ 20°C	2	ECHA
Vapor pressure	40 hPA @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	0.6 (QSAR)	2	EPA, 2019
Water solubility	181 g/L @ 20°C	2	ECHA

Property	Value	Klimisch score	Reference
Flash point	13°C	2	ECHA
Auto flammability	165°C	1	ECHA
Flammability	Highly flammable	-	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

"In two supporting studies on inherent biodegradability, an inherent biodegradability could be shown. However, it is stated in both reports that the elimination could also be related to volatility of the substance and not only to biodegradation. Only in one study, it could be shown by BOD-determination that the test substance was in fact biodegraded." (ECHA)

"Distribution modelling suggests an environmental distribution of crotonaldehyde mainly in soil and water with a low potential of adsorption to soil particles and a medium potential of reaching the air via volatilization from the water surface." (ECHA)

"The substance crotonaldehyde was predicted to have a soil sorption coefficient (Koc) of 10.66 L/kg, corresponding to a log Koc of 1.0277." (ECHA)

"Based on the modelled data it can be shown that the main parts of crotonaldehyde are distributed in soil and water. Only a small part can be found in the air, whereas the distribution in the sediment is negligible." (ECHA)

B. Biodegradation

Crotonaldehyde is readily biodegradable but fails the 10-day window.

In an EPA OTS 796.3200 ready biodegradability:closed bottle test, degradation was 32% after 5 days, 45% after 15 days, and 55% after 28 days (ECHA) [Kl. score = 2].

In an inherent biodegradation test (DIN 38 412 part 25, early draft), degradation was 78% after 5 days, 83% after 10 days, and 94% after 15 days. The COD was 2,060 mg O_2/g test material; the BOD_5 was 320 mgO_2/ g test material; and the BOD_5*100/COD was 15.5% (ECHA) [Kl. score = 2].

In an OECD 301 C (MITI-I) test, degradation was >80% with or without adjustment of the pH to 7.0 at Day 1 of culturing (ECHA) [Kl. score = 2].

In an OECD 301 E test, degradation was 22% after 7 days, 24% after 21 days, and 30% after 28 days (ECHA) [Kl. score = 2].

In an OECD 302 test, degradation was 90% after 19 days. However, similar values were seen in the abiotic control, probably due to the volatilization of the test material (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for crotonaldehyde. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} of 0.6 is 10.66 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.793 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on crotonaldehyde. Crotonaldehyde is not expected to bioaccumulate based on a log K_{ow} of 0.6 (EPA, 2019).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Crotonaldehyde is an acutely toxic compound by oral, dermal and inhalation routes of exposure; it readily penetrates skin and may induce systemic toxicity. Inhalation may induce neurotoxicity. The substance is considered an irritant and/or corrosive to the respiratory tract, skin and eyes. Crotonaldehyde is considered very toxic to the respiratory tract, and the damage caused in one study was found to be non-reversible.

The following sections detail the available and relevant literature on the toxicity of crotonaldehyde. The information described below was obtained from NICNAS IMAP if available and the ECHA database. Please refer to those information sources for the studies referenced therein.

B. Acute Toxicity

Oral

The chemicals are classified as hazardous with the risk phrase ‘Toxic if swallowed’ (T; R25) in HSIS (Safe Work Australia).

Based on a limited number of test results, the chemical has high acute oral toxicity in rats and mice. The median lethal dose (LD50) is 174–300 mg/kg bw in rats and 104–240 mg/kg bw in mice (CICAD, 2008; SCOEL, 2013; MAK, 2012). In an acute oral toxicity fixed

dose study (conducted similarly to the Organisation for Economic Cooperation and Development (OECD) Test Guideline (TG) 420), male and female Sprague Dawley (SD) rats (5 animals/group) were administered the chemical by gavage at doses of 64.5, 107.5, 180, 300 and 500 mg/kg bw and observed for 14 days. Within 24 hours post-treatment, there were 27 out of 50 mortalities, including all animals in the 300 and 500 mg/kg bw groups and 7/10 deaths in the 180 mg/kg bw group. Observed sublethal effects for the surviving animals included lethargy, salivation, changes in motor activity and lacrimation. The LD50 was determined to be 174 mg/kg bw (REACH).

Dermal

The chemica is classified as hazardous with the risk phrase 'Toxic in contact with skin' (T; R24) in HSIS (Safe Work Australia). The available data (rabbit: LD50 128–380 mg/kg bw; guinea pig: 26 mg/kg bw) support this classification (CICAD, 2008; NIOSH, 1979). Reported signs of toxicity include local effects such as necrosis, oedema, erythema and congestion of capillaries, as well as damage to internal organs (REACH). The low LD50 values in two different animal species indicate that the chemical readily penetrates the skin and may induce systemic toxicity.

Inhalation

The chemical is classified as hazardous with the risk phrase 'Very toxic by inhalation' (T+; R26) in HSIS (Safe Work Australia). The available data (median lethal concentration for 4 hours (LC50) 69–120 ppm, equivalent to 0.19–0.34 mg/litre/4h) support this classification (SCOEL, 2013; REACH). Reported signs of toxicity include irritation and neurotoxicity. Examination of the deceased animals revealed haemorrhagic rhinitis, proliferative lesions in the bronchioles, pulmonary congestion and pulmonary oedema as well as haemorrhages of the lung, liver, heart and kidneys (SCOEL, 2013).

C. Irritation

Respiratory Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to respiratory system' (Xi; R37) in HSIS (Safe Work Australia). In a non-guideline study, sensory irritation was quantified by measuring respiratory rate depression upon exposure of B6C3F1 mice to the chemical. The animals were sealed in an airtight vessel and exposed to 5 different concentrations for 10 minutes. The dose resulting in a 50% decrease in respiratory rate (RD50) was determined to be 4.88 ppm. Little or no recovery was reported (REACH).

The substance was also demonstrated to elict neurogenic inflammatory responses in airways of guinea pigs (Andre et al. 2008).

Skin Irritation

The chemical is classified as hazardous with the risk phrase 'Irritating to skin' (Xi; R38) in HSIS (Safe Work Australia). Several available study reports suggest that the chemicals

may be corrosive. However, the older studies on which this was based contained methodological deficiencies and were not conducted according to OECD test guidelines. An EU harmonised classification concluded that the chemical was a skin irritant after consideration of the available data. In the absence of further reliable information, amendment of the existing classification is not warranted.

In a non-guideline study, 0.5 mL of undiluted 2-crotonaldehyde was applied to the abraded and non-abraded skin of rabbits under occlusive conditions. The test substance was allowed to remain on the skin for 4 hours, then signs of irritation or corrosivity were recorded at 4, 24 and 72 hours after exposure and scored on a graded scale of 0–4. The chemical was classified as corrosive to rabbit skin, with maximum scoring attained. No description of the severity and type of skin effects are reported (REACH).

In another non-guideline study, undiluted chemical on intact rabbit skin for 15 minutes produced severe erythema and oedema after 5–9 hours. Hyperaemia appeared immediately after the skin came into contact with the chemical. After 2–3 days desquamation began, the skin became covered with serous crusts and regions of ulceration were seen. Symptoms on the exposed areas persisted for 12–15 days, then gradually healed towards the end of the observation period (2 months). After 15–17 days, partial detachment of necrotised regions of the ear or complete detachment of its distal portion were observed (ECHA). The study results indicated that the chemical was corrosive to rabbit skin.

Eye Irritation

The chemical is classified as hazardous with the risk phrase 'Risk of serious damage to eyes' (Xi; R41) in HSIS (Safe Work Australia). The available data support this classification.

In an eye irritation study, the chemical was found to cause serious damage to rabbit eyes with volumes of 0.001–0.5 mL of undiluted crotonaldehyde applied to the cornea. After 24 hours, the observed eye irritation was described as being equal to that of acetic anhydride, which is corrosive. No reversibility data were reported (REACH).

D. Sensitization

The chemical was not demonstrated to be sensitising in a dose-dependent contact hypersensitivity test in female B6C3F1 mice. The concentrations of the substance crotonaldehyderanged from 0.3 % to 3.0 % in a solution of acetone in olive oil (4:1) for sensitisation and 10 % for the challenge. The mice received 20 µL of the chemical directly on prepared skin for 5 consecutive days. The chemical 2,4-Dinitrofluorobenzene (0.5 % dose) was used as a positive control (REACH; NTP, 1989).

E. Repeated Dose Toxicity

Oral
The chemical is classified as hazardous with the risk phrase 'Danger of serious damage to health by prolonged exposure if swallowed' (Xn; R48/22) in HSIS (Safe Work Australia). While the data are limited, the available data support this classification.

In a 14-day repeated dose oral toxicity study, groups of male and female SD albino rats were administered the chemical in feed at doses of 0, 22, 44, 88 and 175 mg/kg bw/day. No mortality was observed during the study and no evidence of treatment-related toxicity was observed in any of the parameters examined (REACH).

In a 90-day study, rats and mice (10 animals/sex/group) were gavaged with the chemical in doses of 0, 2.5, 5, 10, 20 and 40 mg/kg bw/day for 5 days/week for 13 weeks (REACH; SCOEL, 2013). There were dose-related increases in mortality and in inflammation of the nasal cavity in rats (but not in mice) at doses of 5 mg/kg bw/day and above, with a no observable adverse effect level (NOAEL) of 2.5 mg/kg bw/day established. Lesions of the forestomach were produced in rats at doses of 10 mg/kg bw/day and above (dose-related) and in mice of the highest dose group. However, these data were only presented in a journal abstract and no other details were provided.

In a chronic study, 23–27 male rats were exposed for 113 weeks to the chemical in the drinking water at concentrations of 0, 0.6 and 6 mmol/L (equivalent to 0, 7.3 and 53.9 mg/kg bw/day). The higher dose resulted in reduced body weight gain, while survival was not affected. Nearly half of the high-dose animals had moderate to severe non-neoplastic liver lesions (fatty metamorphosis, focal necrosis, fibrosis and cholestasis) and all the remaining animals (high and low dose) developed liver cell foci (Chung et al, 1986; SCOEL, 2013).

Dermal
Reliable animal studies on the effects of repeated dermal exposure were not available (SCOEL, 2013).

Inhalation
Reliable animal studies are not available (SCOEL, 2013; CICAD, 2008).

In a non-guideline study, rats were continuously exposed to 1.2 mg/m3 of crotonaldehyde for 3 months. Changes in motor activity and blood haemoglobin levels were observed. However, as no pathology or histology studies were undertaken, the data were insufficient to judge the applicability of these results (REACH).

F. Genotoxicity

In Vitro Studies
The substance crotonaldehyde has been found to bind to DNA and induce DNA-protein cross-links in vitro via Michael addition. In a non-guideline study, DNA adducts were

observed in calf thymus DNA treated with 1.0 mM solution of the chemical, either directly or with metabolic activation. The adducts that formed were identified as cyclic 1,N2-propanodeoxyguanosine (REACH). Adducts were also formed in CHO cells (REACH). 'Both the 1- and N2 positions of guanine are involved in base-pairing, hence the presence of the cyclic adduct may lead to mutations' (IARC, 1995).

In an Ames test conducted similarly to OECD TG 471, the substance crotonaldehyde was tested at 0.05–0.4 µL per plate for point mutations against Salmonella typhimurium strains TA 98, 100, 1535, 1537 and 1538 with or without S9 metabolic activation. The chemical had no mutagenic activity in any of the strains tested using the plate incorporation method. However, when a preincubation method was employed, it was mutagenic in S. typhimurium strain TA 100 with and without metabolic activation (REACH; IARC, 1995).

In another Ames test, crotonaldehyde was tested in *S. typhimurium* strains TA 102 and 104 with and without metabolic activation at concentrations of 0.075–1.4 µmol per plate. Using the preincubation method, the chemical was positive for mutagenicity in TA 104 without metabolic activation and negative in TA 102 (REACH; IARC, 1995).

In a non-guideline intrasanguineous mouse host-mediated assay, crotonaldehyde was administered orally (gavage) to CD-1 mice (0.009–0.094 mg/kg bw) during simultaneous intravenous injection of S. typhimurium TA 100. The chemical was found to be mutagenic, with a three-fold increase in revertants of TA 100 recovered from mouse blood compared to the control, at a dose of 0.032 mg/kg bw (REACH; CICAD, 2008; MAK, 2012).

In a sister chromatid exchange assay in mammalian cells conducted similarly to OECD TG 479, crotonaldehyde was tested in Chinese hamster ovary (CHO) cells. The results were positive from 0.5 µg/mL and above without activation (dose range tested: 0.16–1.6 µg/mL), and positive from 1.6 µg/mL with S9 metabolic activation (dose range tested: 1.6–160 µg/mL) (REACH). Positive results were also observed in other sister chromatid exchange studies carried out on human blood lymphocytes and lymphoblastoid Namalva cells (REACH).

In a mammalian chromosome aberration assay conducted similarly to OECD TG 473, crotonaldehyde was tested in CHO cells with positive results from 1.6 µg/mL onwards without metabolic activation (dose range tested: 0.5–5 µg/mL) and positive at the highest dose tested (16 µg/mL) with S9 metabolic activation (dose range tested: 1.6–16 µg/mL) (REACH). In another chromosome aberration study in human blood lymphocytes and lymphoblastoid Namalva cells (dose range tested: 5–250 µM), increased micronuclei were observed from 200 µM and above for lymphocytes, and from 100 µM and above for Namalva cells (REACH).

In a SOS-Chromotest, DNA repair functions were induced in Escherichia coli PQ37 using ethanol as a solvent instead of dimethyl sulfoxide (DMSO). A weak SOS result was obtained using the S. typhimurium strain TA1535/pSK1002 without metabolic activation (IARC, 1995; SCOEL, 2013; CICAD, 2008).

The substance crotonaldehyde has been tested for mutagenic activity in several other in vitro assays, including DNA damage and repair assays in mammalian and bacterial cells. Positive results were obtained in primary rat epithelial cells (stomach and colon). However, in a test conducted similarly to OECD TG 482, no unscheduled DNA synthesis was observed in a single DNA repair test in rat hepatocytes (REACH).

In Vivo Studies

In a study conducted similarly to OECD TG 475, chromosomal aberrations were observed in mouse bone marrow cells after 12 hours when the animals were administered a single dose of the chemical (8, 16, 32, or 200 µL/kg bw) by i.p. injection (REACH).

In a non-guideline study, crotonaldehyde was found to covalently bind to DNA and form cyclic DNA adducts in the dermis of Sencar mouse skin after topical application of the chemical (total dose 1.4 mmol, 98 mg) five times per week for three weeks (IARC, 1995; MAK, 2012). No background adducts were found in the skin of untreated mice. Systemic availability of the chemical was demonstrated by increased numbers of DNA adducts in the liver, lung and kidneys of rats after administration of crotonaldehyde at high doses via gavage (IARC, 1995; MAK, 2012).

In a study conducted similarly to OECD TG 477, sex-linked recessive lethal mutations and reciprocal translocations were induced in D. melanogaster injected with a single dose of crotonaldehyde at 3500 ppm (IARC, 1995; REACH). In another study, crotonaldehyde (4000 ppm) was administered to D. melanogaster via oral feeding, although the chemical was not found to be mutagenic after three days.

In a study conducted similarly to OECD TG 483, crotonaldehyde induced chromosomal damage in the spermatogonia of mice after oral administration in drinking-water or by i.p. injection. Special meiotic anomalies, such as degenerated cell nuclei, multispindle cells, polyploids and sperm anomalies were observed. However, no positive and negative controls were reported, rendering this study inadequate for the evaluation of germ cell mutagenicity (IARC, 1995; MAK, 2012; REACH). In another study conducted similarly to OECD TG 478, dominant lethal frequencies increased with dose (8, 16 or 32 µL/kg bw) in a mouse study following i.p. administration (REACH).

G. Carcinogenicity

The International Agency for Research on Cancer (IARC) has classified the chemical as 'Not classifiable as to its carcinogenicity to humans' (Group 3) (IARC, 1995) based on inadequate evidence for carcinogenicity in humans and animals.

In a single, non-guideline study, the trans isomer (E-crotonaldehyde, CAS No. 123-73-9) was administered to male Fischer 344 (F344) rats (23–27 animals/group) in drinking water at 0, 0.6 or 6.0 mM (equivalent to 0, 7.3 and 53.9 mg/kg bw/day) for 113 weeks (Chung et al., 1986). There were statistically significant increases in the incidence of hepatocellular neoplasms (including neoplastic nodules and hepatocellular carcinomas) in the low dose group. The incidences were 0/23, 9/27 and 1/23 in the control, low- and high-dose groups, respectively. The incidences of hepatocellular carcinomas alone were 0/23, 2/27 and 0/23, respectively. The incidences of enzyme-altered liver foci, which are considered precursors of neoplasms, were 1/23, 23/27 and 13/23 in the control, low- and high-dose groups, respectively. The increased incidences in both the low- and high-dose groups were statistically significant relative to controls. The lower incidence of neoplastic and preneoplastic lesions at the higher dose compared with the higher dose was not explained. However, the study was only carried out on a single sex and only using two doses. In addition, the incidence of tumours did not appear to be dose-related (IARC; Chung et al., 1986).

H. Reproductive and Developmental Toxicity

In a one-generation reproductive toxicity study, no reproductive effects were seen at the doses tested. The available information does not meet the criteria for hazard classification in regards to reproductive toxicity.

In a one-generation reproductive toxicity study carried out similarly to OECD TG 415, male and female F344 rats were treated with the chemical (0, 2.5, 5 and 10 mg/kg bw/day) by gavage daily until sacrifice. Males were dosed for 61 days prior to breeding, and females were dosed 31 days prior to breeding. There were no notable clinical observations with regards to gonadal function, mating behaviour or fertility in either male or female rats. A NOAEL of 10 mg/kg bw/day for both sexes was established for reproductive effects (REACH).

In another study, a single i.p. injection of crotonaldehyde (0, 8, 16 or 32 µL/kg bw, corresponding to 0, 6.8, 13.7 and 27.2 µg/kg bw) was administered to male Swiss albino mice. A statistically significant increase in the percentage of abnormal sperm heads was recorded at 16 and 32 µL/kg bw at 3 weeks, and at only the highest dose at 5 weeks. However, there were methodological deficiencies in this study, and the route of exposure is not appropriate for humans (REACH).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for crotonaldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is 2.5 mg/kg-day based on reduced body weights, increased nasal tumors, histopathological findings in rats from 9-day oral gavage study (Kl = 2). The NOAEL of 2.5 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 2.5/(10 x 10 x 1 x 3 x 1) = 2.5/300 = 0.008 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.008 x 70 x 0.1)/2 = 0.03 mg/L

B. Cancer

Crotonaldehyde is not carcinogenic, so no cancer reference value was developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Crotonaldehyde is a flammable liquid.

Crotonaldehyde does not exhibit the following physico-chemical properties:
· Explosivity
· Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance exhibits a relatively high degree of acute and chronic aquatic toxicity as discussed below.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on crotonaldehyde.

Table 2: Acute Aquatic Toxicity Studies on Crotonaldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hr LC_{50}	0.65	1	ECHA
Pimephales promelas	96-hr LC_{50}	0.84	1	ECHA
Lepomis macrochirus	96-hr LC_{50}	3.0	2	ECHA
Daphnia magna	48-hr EC_{50}	2	1	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50} 96-hr EC_{50}	0.597 <0.881	1	ECHA

Chronic Studies

The 41-d NOEC to *Oryzias latipes* in an OECD 210 fish early life stage toxicity test is 0.0247 mg/L (ECHA) [Kl. score = 1].

The 96-hr EC_{10} to *Pseudokirschneriella subcapitata* is <0.385 mg/L based on growth rate (ECHA) [Kl. score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for crotonaldehdye follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (0.65 mg/L), invertebrates (50 mg/L), and algae (0.597 mg/L). Results from chronic studies are available for fish (0.0247 mg/L) and algae (<0.385 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term results studies for two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC or EC_{10} value of 0.0247 mg/L for fish. The $PNEC_{water}$ is 0.0005 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.00007 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.21/1500) \times 1000 \times 0.0005$
$= 0.00007$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 10.66 \times 0.02$
$= 0.21$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for crotonaldehyde based on the log K_{ow} is 10.66 L/kg (EPA, 2018).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Crotonaldehyde is readily biodegradable but failing the 10-day window; thus, it does not meet the screening criteria for persistence.

Based on an estimated log K_{ow} of 0.6, crotonaldehyde does not meet the screening criteria for bioaccumulation.

The lowest chronic NOEC or EC_{10} value for crotonaldehyde is <0.1 mg/L. The acute $E(L)C_{50}$ values are <1 mg/L for fish and algae. Thus, crotonaldehyde meets the screening criteria for toxicity.

The overall conclusion is that crotonaldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute toxicity – category 1
Acute toxicity – category 3
Skin irritation – category 2
Eye damage – category 1
Germ cell mutagenicity – category 1B
Specific target organ toxicity (single exposure) – category 3
Specific target organ toxicity (repeated exposure) – category 2
Flammable liquid – category 2
Hazardous to the aquatic environment (acute) – category 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a poison center or doctor/physician.

Skin Contact
Immediately call a poison center or doctor/physician. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical advice/attention. Take off immediately all contaminated clothing. Rinse skin with soap and water/shower.

Inhalation
Remove victim to fresh air and keep at rest in a position comfortable for breathing. Immediately call a poison center or doctor/physician.

Ingestion
Immediately call a poison center or doctor/physician. Rinse mouth. If swallowed give 1-2 glasses of water to drink immediately

Notes to Physician Vapours may cause irritation to the eyes, respiratory system and the skin. Treatment: Treat symptomatically. In case of lung irritation first treatment with dexametason aerosol (spray). If ingested, irrigate the stomach.

Medical Conditions Aggravated by Exposure
Respiratory disorder

Emergency Personnel Protection
No data available.

B. Fire Fighting Information

Extinguishing Media
Foam, Dry chemical, carbon dioxide (CO2)
Do not use a solid water stream as it may scatter and spread fire.

Note: Cool containers / tanks with water spray. Dike and collect water used to fight fire.

Specific Exposure Hazards
Under conditions giving incomplete combustion, hazardous gases produced may consist of carbon monoxide, carbon dioxide (CO2). Combustion gases of organic materials must in principle be graded as inhalation poisons

Special Protective Equipment for Firefighters
Self-contained breathing apparatus

C. Accidental Release Measures

Personal Precautions
Avoid contact with the skin and the eyes. Keep away from heat and sources of ignition. Provide adequate ventilation

Environmental Precautions
Prevent further leakage or spillage. Do not discharge into the drains/surface waters/groundwater. Product is very toxic to aquatic life with long lasting effects

Steps to be Taken if Material is Released or Spilled
Soak up with inert absorbent material. Do not use rags, paper towels or combustible materials to clean up a spill, because spontaneous combustion can occur. Keep in suitable, closed containers for disposal. Dispose of in accordance with local regulations

D. Storage and Handling

General Handling
Advice on safe handling: vapors may form explosive mixtures with air. The pressure in sealed containers can increase under the influence of heat. Refill and handle product only in closed system. Provide sufficient air exchange and/or exhaust in work rooms. Protection - fire and explosion: : Keep away from sources of ignition - No smoking. Vapours are heavier than air and may spread along floors. Take necessary action to avoid static electricity discharge. Ground and bond containers when transferring material.

Other Handling Precautions
In case of fire, emergency cooling with water spray should be available.

Storage
The product will oxidize in air and release heat. Oxidization creates acids and peroxides, that may lead to corrosive damages in storage and handling equipment. Technical measures/Storage conditions: Keep tightly closed in a dry, cool and well-ventilated place. Handle and open container with care. May need to store under nitrogen. Incompatible products: Keep away from: acids, bases, amines, oxygen, oxidizing agents, reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for crotonaldehyde in Australia is 2 ppm (5.7 mg/m3) as an 8-hr TWA. No STEL is available.

Engineering Controls
General or dilution ventilation is frequently insufficient as the sole means of controlling employee exposure. Local ventilation is usually preferred. Explosion-proof equipment (for example fans, switches, and grounded ducts) should be used in mechanical ventilation systems.

Personal Protection Equipment
Respiratory Protection:
Respirator or full mask in accordance with guidance - or self-contained breathing apparatus

Hand Protection:
Chemical-resistant gloves. Suitable material: butyl-rubber Type: Butoject (Company KCL) or comparable; or refer to glove manufacturer's recommendation.

Skin Protection:
Impervious clothing

Eye protection:
Wear appropriate protective eyeglasses or tightly fitting chemical safety goggles. In addition to goggles, wear a face shield if there is a reasonable chance for splash to the face.

Other Precautions:
General advice: Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Use only in an area equipped with a safety shower. Make sure eye wash fountain is available. Hygiene measures: When using, do not eat, drink or smoke. Take off all contaminated clothing immediately. Wash hands before breaks and immediately after handling the product.

F. Transport Information

UN Number 1143
Hazard class 6.1

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

DIETHANOLAMINE

This dossier on diethanolamine (DEA) presents the most critical studies pertinent to the risk assessment of diethanolamine in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2,2'-iminodiethanol

CAS RN: 111-42-2

Molecular formula: $C_4H_{11}NO_2$

Molecular weight: 105.14

Synonyms: Diethanolamine; 2,2'-iminodiethanol; 2,2'-dihydroxydiethylamine; 2-[(2-hydroxyethyl)amino]ethanol; bis(2-hydroxyethyl)amine; DEA; di(2-hydroxyethyl)amine; ethanol, 2,2'-iminobis-(9Cl); ethanol, 2,2'iminodi-(8Cl)

SMILES: C(CO)NCCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diethanolamine

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Crystals (prisms) or syrupy liquid (>82°F)	2	ECHA
Melting Point	27°C	1	ECHA
Boiling Point	268.9°C (decomposition occurs ≥200°C)	1	ECHA
Density	1.095.3 kg/m^3	2	ECHA
Vapor Pressure	1 hPa @ 108°C (measured); 0 hPa at 25°C	2	ECHA

Property	Value	Klimisch score	Reference
Partition Coefficient (log K_{ow})	-2.46 @ 25°C	2	ECHA
Water Solubility	Miscible	2	ECHA
Flash Point	176°C @ 1,013 hPa	2	ECHA
Auto flammability	375°C @ 1,013 hPa	1	ECHA
Flammable	Not flammable	1	ECHA
Viscosity	390.9 mPa s @ 30°C; 102.7 mPa s @ 50°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Diethanolamine is readily biodegradable. It is not expected to bioaccumulate, and it has low potential to adsorb to soil.

B. Biodegradation

Diethanolamine is readily biodegradable. In an OECD 301F test, there was 50% degradation after 7 days, 80% after 14 days, and 93% after 28 days (OECD 2007; ECHA) [Kl. score = 1]. In a "Ready" Biodegradability – Dissolved Organic Carbon (DOC) Die-Away test, there was 86% degradation after 7 days and 96% degradation after 10 days (ECHA) [Kl. score = 2]. In modified OECD 301E screening tests using river or pond water, there was 93% and 97% degradation (measured as DOC removal) after 28 days (OECD 2007; ECHA) [Kl. score = 2].

C. Environmental Distribution

<u>Distribution Modeling</u>

No experimental data are available for diethanolamine. The K_{oc} for diethanolamine (as the charged molecule) was calculated to be 10 at pH values between 5 and 8 (Franco and Trapp, 2008; Franco et al., 2009; ECHA). [Kl. score = 2]

D. Bioaccumulation

There are no bioaccumulation studies on diethanolamine. The BCF was estimated to be 2.3 based on calculations from OASIS Catalogic v.5.11.15 [BCF base-line model v.0208] (Dimitrov et al., 2005; ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Diethanolamine exhibits moderate acute toxicity by the oral route, but low acute toxicity by the inhalation and dermal routes. It is a skin irritant and a severe eye irritant. Diethanolamine is not a skin sensitizer. Repeated oral exposure to rats (in drinking water) resulted in anemia, kidney toxicity, demyelinization of the brain/spinal cord, and damage to the testes in males, which included adverse effects on the sperm. Repeated oral exposure to mice (in drinking water) resulted in adverse effects to the kidney, liver, and heart. Repeated dermal exposure to rats and mice resulted in systemic toxicity, which included kidney toxicity, anemia (rats only), and liver toxicity (mice only). Rats exposed nose-only to an aerosol of diethanolamine developed anemia, adaptive liver and kidney effects, damage to the male reproductive organs, and upper respiratory tract irritation. There was no evidence of neurotoxicity. In short-term oral studies, rats and mice exposed to diethanolamine showed some immune-modulating effects at dose levels that resulted in overt signs of systemic toxicity. Diethanolamine was not genotoxic in a variety of *in vitro* and *in vivo* genotoxicity tests. Diethanolamine was not carcinogenic to rats in a two-year NTP dermal bioassay; but, in mice, there was an increased incidence of liver tumors in males and females and kidney tumors in males. Studies by the oral and dermal routes showed testicular damage in male rats, but no adverse effects in female reproductive organs. Developmental toxicity, coincident with maternal toxicity, occurred in rats when exposures by the oral, dermal, or inhalation routes. There was no developmental toxicity in rabbits even at doses that caused maternal toxicity.

B. Pharmacokinetics/Metabolism

Following oral administration of [^{14}C]-diethanolamine, 57% of the dose was absorbed (Matthews et al., 1997). Absorption was lower through the skin than from oral administration. Diethanolamine may also facilitate its own absorption in rats, as 3% and 16% of the dermally applied doses (in 95% ethanol) of 2 and 27 mg/kg, respectively, were absorbed through the skin in a 48-hour period. Dermal absorption of diethanolamine is higher in the mouse than the rat: absorption was 25 to 60% from dermal doses of 8 to 80 mg/kg (Matthews et al., 1997).

The distribution of diethanolamine is similar across all routes of exposure (Matthews et al., 1997; Mendrala et al., 2001). The highest concentrations were found in the liver and

kidney. The half-life of diethanolamine from tissues is about 6-7 days (Mendrala et al., 2001).

Following an oral dose of [^{14}C]diethanolamine to male F344 rats, the livers showed levels of un-metabolized diethanolamine, N-methyl-diethanolamine, N,N-dimethyl-diethanolamine, and phosphates of diethanolamine. In addition, the organic extract of the liver had radioactivity co-eluting with phosphatidyl ethanolamine and phosphatidyl choline. When the organic extract was digested with sphingomyelinase, 30% of the phospholipids were identified as ceramides and the remaining 70% as phosphoglycerides. Incubation of human liver slices with [^{14}C]-diethanolamine showed similar incorporation of diethanolamine into ceramides, followed by methylation (Matthews et al., 1995).

Diethanolamine is excreted primarily in urine as the parent compound (25-36%), with lesser amounts of O-phosphorylated and N-methylated metabolites (Matthews et al., 1997).

C. Acute Toxicity

The oral LD_{50} value for male and female rats combined was determined to be 1,600 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} in female Wistar rats is 1,820 mg/kg (ECHA) [Kl. score = 2].

There were no deaths in rats following an 8-hour inhalation exposure to an atmosphere enriched with diethanolamine vapor. The technically highest attainable concentration is 1.9 mg/m^3 or 0.44 ppm (ECHA) [Kl. score = 2]. There were no deaths in rats following an 8-hour exposure to 0.2 mg/L diethanolamine vapor (ECHA) [Kl. score = 2].

There are no reliable acute dermal toxicity studies on diethanolamine.

D. Irritation

Application of 2 mL of diethanolamine to the skin of rabbits for 20 hours was irritating. The mean of the 24, 48, and 72 hours scores were 2.00 for erythema and 1.33 for edema (ECHA) [Kl. score = 2].

Instillation of diethanolamine into the eyes of rabbits was irritating. The mean of the 24, 48, and 72 hour scores were 1.67 for corneal opacity; 0.00 for iridial lesions; 1.50 for conjunctival redness; and 0.83 for chemosis. Corneal lesions still persisted in one of two animals at the end of the 8-day observation period (ECHA) [Kl. score = 2]. Instillation of 100 mg diethanolamine into the eyes of rabbits produced a mean irritation score based on Kay and Calandra of 50.75, indicating severe irritation (ECHA) [Kl. score = 2].

E. Sensitization

Diethanolamine was not considered a skin sensitizer in a guinea pig maximisation test (ECHA). [Kl. score = 1]

F. Repeated Dose Toxicity

Oral

Male and female F344 rats were given diethanolamine in their drinking water for 13 weeks at concentrations of 0, 320, 630, 1,250, 2,500, or 5,000 ppm for males; and 0, 160, 320, 630, 1,250, or 2,500 ppm for females. The average daily intakes were estimated to be: 0, 25, 48, 97, 2,202, or 436 mg/kg-day for males; and 0, 14, 32, 57, 124, or 242 mg/kg-day for females. In the top dose group, 2/10 males died during the study. Weight gain was reduced in the ≥630 ppm males and the ≥320 ppm females. Decreased water consumption among the higher dose groups may have contributed in part to the decreased body weight gain. Clinical signs of toxicity included tremors, emaciation, abnormal posture, and rough hair coat in the two highest dose groups. A dose-dependent microcytic, normochromic anemia was seen in all dose groups for both sexes. Hematologic effects included decreases in erythrocyte and reticulocyte counts, hemoglobin concentration, hematocrit, MCV, and MCH. MCV was reduced in rats at all dose levels. Hematologic effects were not associated with microscopic changes in the femoral bone marrow. Relative kidney weights were increased in a dose-dependent manner in the ≥320 ppm males and ≥160 ppm females, accompanied by increases in the incidence and/or severity of nephropathy, renal tubular cell necrosis, or tubular mineralization. Nephropathy consisted of tubules lined by epithelial cells with more basophilic staining of the cytoplasm and a higher nuclear/cytoplasmic ratio; occasionally, thickened basement membranes were seen around these tubules. This lesion was present to a minimal degree in controls, particularly in male rats, but was increased in incidence and severity in the 5,000 ppm males and in most of the groups of treated females. Increased nephropathy was considered a regenerative change and was supported by the observation of tubular necrosis at the higher dose groups. Relative liver weights were increased in the ≥630 ppm males and ≥320 ppm females, with no corresponding histopathological changes in the liver. There was, however, mild to moderate increases in serum levels of total bile acids in the ≥160 ppm females and in the ≥630 ppm males. Decreases in testis and epididymis weights (≥1,250 ppm) were associated microscopically with degeneration of seminiferous epithelium and with hypospermia (≥2,500 ppm). Testicular degeneration was diagnosed in all high-dose males and in 3/10 of the 2,500 ppm males. Intraluminal cellular debris and reduced numbers of sperm cells were present in the epididymis. These findings correlated with decreases in sperm motility and sperm count per gram caudal tissue. There was also atrophy of the seminal vesicle and prostate glands in the higher dose group males. In females, the estrous cycle length was similar across all groups. Minimal to mild demyelination of the brain and spinal cord was noted in the ≥2,500 ppm males and the ≥1,250 ppm females; there were no neurological clinical signs that could be attributed

to these lesions. Cytoplasmic vacuolization of the zona glomerulosa of the adrenal cortex was seen in the 5,000 ppm males and in the ≥1,250 ppm females. This was a minimal change consisting of small clear vacuoles in the cytoplasm of these cells and may have been related to increased mineralocorticoid production secondary to kidney damage and/or dehydration. The most sensitive endpoints were the microcytic anemia in both sexes and kidney effects in females (weight, nephrotoxicity) and males (weights). The LOAELs are 320 ppm (25 mg/kg-day) for males and 160 ppm (14 mg/kg-day) for females (NTP 1992; Melnick et al., 1994a). [Kl. score = 1]

Male and female B6C3F1 mice were given diethanolamine in their drinking water at concentrations of 0, 630, 1,250, 2,500, 5,000 or 10,000 ppm for 13 weeks. The average daily intakes were estimated to be: 0, 104, 178, 442, 807, or 1,674 mg/kg-day for males; and 0, 142, 347, 884, 1,154, or 1,128 mg/kg-day for females. All of the ≥5,000 ppm animals and 3/10 of the 2,500 ppm females died during the study. Body weight gains were lower in the 2,500 ppm males and in the 1,250 and 2,500 ppm females. Animals that survived to the end of the study had similar water consumption compared to the controls. Clinical signs in the animals that died early in the 2,500 ppm group were tremors, ruffled fur, emaciated appearance, abnormal posture, and hypoactivity. There was no significant gross findings at necropsy in the mice that died early or survived to study termination. Absolute and relative liver weights were increased in a dose-dependent manner in male and female mice and was associated with increases in serum alanine aminotransferase and sorbital hydrogenase activities and, in addition, microscopic changes diagnosed as hepatocellular cytologic alteration and necrosis. Cytologic alteration consisted of multiple hepatocyte changes including hypertrophy with increased eosinophilia and disruption of hepatic cords. These lesions were observed in mice that died early and those that survived to the end of the study. There was also increased nuclear pleomorphism and the frequent presence of large, multinucleated hepatocytes. These “giant” cells often contained 10 or more nuclei. Hepatocyte necrosis was randomly distributed and involved single cells or small foci. Absolute and relative kidney weights were increased in males and were associated with a dose-dependent increase in the incidence of nephropathy among those mice that survived to the end of the study. Nephropathy was minimal; there were renal tubules lined by basophilic cells with high nuclear/cytoplasmic ratio. This was considered to be a regenerative response, although active tubular necrosis was observed only in a few early-death mice at ≥5,000 ppm. Increased heart weight was seen in the 2,500 ppm females, and relative heart weight was seen in the 2,500 ppm males and the 1,250 and 2,500 ppm females. There was also minimal-to-marked degeneration and necrosis of cardiac myocytes in both sexes exposed to ≥2,500 ppm. Myocardial degeneration was generally more severe in mice that died early than in those that survived to study termination. The most sensitive endpoint was the increase in liver weights with corresponding histopathological changes. The LOAEL was 630 ppm (104 and 142 mg/kg-day in males and females, respectively) (NTP, 1992; Melnick *et al.*, 1992b). [Kl. score = 1]

Inhalation

Male and female Wistar rats were exposed nose-only to 0, 15, 150, or 450 mg/m^3 diethanolamine aerosol, 6 hours/day, 5 days/week for 90 days. The MMAD values were 1.1 – 1.9 µm, 1.0 µm, and 0.6 – 0.9 µm for the 15, 150, and 450 mg/m^3 exposure groups, respectively. The percent aerosol ranged among the exposure groups, from 92 to 95%. There were no deaths during the study. The 400 mg/m^3 males had slightly decreased body weights. The neurotoxicity endpoints (functional observation battery, sensorimotor test/reflexes, and motor activity) and ophthalmoscopy examination showed no treatment-related effects. At 400 mg/m^3, there was a significant decrease in red blood cells, hemoglobin, hematocrit, and mean corpuscular volume in both sexes. A marginal increase in anisocytosis was seen in the 400 mg/m^3 males; and no treatment-related effects were seen in white or differential blood counts. ALP serum activity was increase in the ≥150 mg/m^3 animals, and reduced ALT in the ≥150 mg/m^3 males. Blood chemistry changes included increased calcium, total protein, albumin, globulin in the ≥150 mg/m^3 females; and increased total protein and albumin in the ≥150 mg/m^3 males as a trend. Absolute and relative liver and kidney weights were increased in the ≥150 mg/m^3 animals. Histopathologic examination showed diffuse testicular atrophy accompanied by oligozoospermia in the epididymides, and slight prostate atrophy in the some of the 400 mg/m^3 males. There was also minimal or slight tubular hyperplasia of the kidney in some females as well as intratubular lithiasis in increased number (also in the 400 mg/m^3 males). There was also indications of local irritation of the respiratory tract. The larynx appeared to be the most sensitive area where some epithelia damage was observed at all concentrations. Focal inflammation at the tracheal bifurcation occurred in the ≥150 mg/m^3 animals. No treatment-related effects were seen in the neuropathologic examination. The NOAEC for systemic toxicity is 15 mg/m^3. The LOAEC for localized effects (irritation) is 15 mg/m^3; a NOAEC was not established (Garner et al., 2008). [Kl. score = 1]

Male and female Wistar rats were exposed nose-only to 0, 1.5, 3, or 8 mg/m^3 diethanolamine aerosol, 6 hours/day, 5 days/week for 90 days. Additional group of female rats were exposed for 90 days followed by a 3-month recovery period. The MMAD values were 0.6 µm, 0.6 µm, and 0.7 µm for the 1.5, 3, and 8 mg/m^3 exposure groups, respectively. At 8 mg/m^3, the animals showed upper respiratory tract irritation in the form of squamous metaplasia of the laryngeal epithelium at the base of the epiglottis; this was accompanied by some inflammatory cell infiltration. These effects were reversible following the 3-month recovery period. The NOAEC for localized effects (irritation) is 3 mg/m^3 (ECHA). [Kl. score = 1]

Dermal

Male and female F344 rats were given daily dermal applications of 0, 32, 63, 125, 250, or 500 mg/kg diethanolamine, 5 days/week for 13 weeks. The animals that died during the study are as follows: one 500 mg/kg male during week 9 and 2 500 mg/kg females

that were killed in a moribund condition during week 10. Final mean body weights were lower in the ≥250 mg/kg male and the ≥125 mg/kg females. The primary clinical signs of toxicity in the ≥125 mg/kg animals were irritation and crusting of the skin at the application site. In all dosed groups, there was a moderate, poorly regenerative, microcytic, normochromic anemia in both sexes. Red blood cell variables were decreased in the ≥32 mg/kg dose groups. There were no histologic changes in the femoral bone marrow in any dose group. Serum biochemical changes in males were increased UN and albumin in the 63 and 250 mg/kg groups, respectively, and mild increases in ALT in the ≥125 mg/kg animals. In females, UN, albumin, and total protein increased in the ≥32 mg/kg groups (≥63 mg/kg for total protein), and total bile acids increased in the ≥250 mg/kg groups. A mild increase was seen in ALT in the 500 mg/kg females. The kidney was a target organ. Absolute and relative kidney weights in male and female rats; these were associated with increased severity or increased incidences of nephropathy, renal tubular cell necrosis, or tubular mineralization. The incidence and severity of nephropathy was increased in a dose-dependent manner at the lower dose levels in females, but there was no clear treatment effect on this lesion in males. Tubular necrosis was observed in the ≥250 mg/kg females, but no active necrosis was found in the corresponding male groups. Tubular mineralization, consistent with previous necrosis, was present in the 500 mg/kg males, as well as being increased in incidence and severity in most treated female groups. The absolute and relative liver weights were increased in a dose-dependent manner in both sexes; there were no corresponding histopathologic changes even though there were some mild serum biochemical changes. There were no adverse effects on the testes or epididymides; sperm morphology and vaginal cytology was unaffected by treatment. The skin lesions were dose-related in incidence and severity, and consisted of ulcers, chronic active inflammation, acanthosis, and hyperkeratosis. Demyelination in the medulla oblongata was observed in the 500 mg/kg animals, and in seven 250 mg/kg females; the lesions were characterized by intramyelinic vacuoles arranged symmetrically around the medial medulla oblongata in the region of the tectospinal tract. The lesions were minimal in severity and there was no spinal cord involvement. The LOAEL for this study is 32 mg/kg-day; a NOAEL was not established (NTP, 1992; Melnick et al., 1994a). [Kl. score = 1]

Male and female B6C3F$_1$ mice were given daily dermal applications of 0, 80, 160, 320, 630, and 1,250 mg/kg diethanolamine, 5 days/week for 13 weeks. At 1,250 mg/kg, there were early deaths and reduced body weight gain. Skin lesions were seen in the ≥80 mg/kg groups, there was acanthosis at 80 mg/kg and with a dose-dependent increased incidence up to ulcerations, inflammation, and hyperkeratosis at the higher levels. Liver weights were increased in a dose-dependent manner in the ≥32 mg/kg groups and were associated with morphological alterations in the liver in the ≥32 mg/kg groups. Kidney weights were increased in a dose-dependent manner in the ≥32 mg/kg groups with an increased incidence of tubular necrosis only in the 1,250 mg/kg group. There was also degeneration in the heart and cytologic alterations in the salivary gland

in the 1,250 mg/kg group only. The LOAEL for this study is 80 mg/kg-day; a NOAEL was not established (NTP, 1992;Melnick et al., 1994b) [Kl. score = 1]

G. Genotoxicity

In Vitro Studies

Table 2 presents the results of the *in vitro* genotoxicity studies on diethanolamine.

Table 2: *In vitro* Genotoxicity Studies on Diethanolamine

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	Dean et al. (1985)
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Haworth et al. (1983)
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	2	Myhr et al. (1986)
Chromosomal aberration (rat liver cells RL1 and RL4)	-	NA	2	Dean et al. (1985)
Chromosomal aberrations (CHO cells)	-	-	2	Loveday et al. (1989)
Sister chromatid exchange (CHO cells)	-	-	2	Loveday et al. (1989)

*+, positive; -, negative; NA, not applicable

In vivo Studies

Male and female B6C3F_1 mice were given daily dermal applications of 0, 80, 160, 320, 630, or 1,250 mg/kg diethanolamine for 13 weeks. There was no induction of micronuclei in the peripheral blood erythrocytes at any dose level (NTP, 1992; Witt et al., 2000) [Kl. score = 1].

H. Carcinogenicity

Oral
No studies are available.

Inhalation
No studies are available.

Dermal
Male and female F344/N rats were given dermal application of diethanolamine for 104 weeks. For males, the doses were 0, 16, 32 or 64 mg/kg-day; and for females, the doses were 0, 8, 16 or 32 mg/kg-day. There was no difference in survival rates between treated and control animals. Mean body weights were lower in the 64 mg/kg-day males from week 8 to 89 and in the 32 mg/kg-day females from week 97 compared to the control animals. The incidences of tumors was not increased in the treated groups compared to the controls. (NTP, 1999). [Kl. score = 1]

Male and female $B6C3F_1$ mice were given dermal applications of 0, 40, 80 or 160 mg/kg-day diethanolamine by dermal application for 104 weeks. There was reduced survival in the treated female mice (88, 66, 66, and 46% for the 0, 40, 80 and 160 mg/kg-day groups, respectively). This was attributed to liver tumors. No differences were seen in survival rates in the treated male mice compared to the controls. Mean body weights in the 80 and 160 mg/kg-day males were lower than those in the control animals after week 88. Mean body weights in the treated female mice were lower than those of the controls from week 73 (40 and 80 mg/kg-day) and week 53 (160 mg/kg-day).

The incidence of hepatocellular adenomas and of hepatocellular adenomas and carcinomas (combined) were significantly increased in all male and female dose groups, while the incidences of hepatoblastoma was increased in the mid- and high-dose groups. In the female mice, the incidences of hepatocellular neoplasms were significantly higher in all dosed groups compared to the control. Non-neoplastic lesions were seen only in the liver of all male and female dose groups and consisted of cytoplasmic alteration, characterized by mild to moderate enlargement of centrilobular hepatocytes, and syncytial alteration, characterized by scattered hepatocytes with three or more small nuclei.

The incidence of renal tubule adenomas was also increased in males with a positive trend, but the incidences of carcinoma and hyperplasia did not follow this pattern. A step section evaluation found additional adenomas and hyperplasias in all treated male groups. The combined analysis of single and step sections indicated a dose-related increase in the incidence of renal hyperplasia and renal tubule adenoma or carcinoma (combined), and increase in the incidences of renal tubule adenoma in male mice (NTP, 1999). [Kl. score = 1]

Mode-of-Action for Mouse Liver Tumors in DEA-exposed Mice
Effects of DEA on choline homeostasis

Dietary choline deficiency or deprivation induces liver tumors in rodents (Newberne *et al.*, 1982). In contrast, dietary supplementation of choline with or without methionine reduces the incidence of liver tumors in carcinogen-treated mice (Fullerton *et al.* 1990; Newberne *et al.*, 1990). DEA is structurally similar to ethanolamine and choline, important endogenous precursors for normal membrane structure and function. Choline is also oxidized to betaine, an essential methyl group donor in 1-carbon metabolism. The mechanisms by which choline deficiency is thought to be carcinogenic include enhanced cell proliferation, altered methylation status, and altered signal transduction (Rogers, 1995; Zeisel, 1996; Zeisel and Blustjazn, 1994). The development of intracellular choline deficiency as the mode of action by which DEA cause the mouse liver tumors observed in the NTP bioassay is supported by the following experimental evidence:

1. $B6C3F_1$ mice dosed dermally with 160 mg/kg DEA, 5 days/week for 2 weeks showed a marked decrease in choline metabolites and S-adenosylmethionine (SAM) levels in their livers similar to animals kept on a choline-devoid diet, indicating the development of choline deficiency. These effects were reversed following a 2-week recovery period (Lehman-MeKeeman *et al.*, 2002). A significant reduction in the hepatic levels of choline metabolites, including choline, phosphocholine, and glycerophospho-choline, and SAM levels was also reported by Stott *et al.* (2000) with $B6C3F_1$ mice dosed in a similar regimen with DEA via dermal and/or oral routes.

2. $B6C3F_1$ mice have a much lower ability than C57Bl/6 mice to maintain nascent methylation capacity, a characteristic that is believed to contribute to a higher spontaneous liver tumor incidence in $B6C3F_1$ mice (Counts *et al.*, 1996). In a study by Lehman-McKeeman *et al.*, (2002), choline deficiency, as evidenced by changes in phosphocholine concentrations, was produced in both strains of mice. However, unlike the $B6C3F_1$ mouse, DEA did not alter SAM concentrations in the C57Bl/6 strain.

3. DEA is incorporated into rat liver phospholipids (Barbee and Hartung, 1979; Mathews *et al.*, 1995) and can alter the biosynthesis of hepatic phosphatidylethanolamine and phosphatidylcholine (PC). In cultured cells, DEA inhibited cellular uptake of choline, decreased PC synthesis, and became incorporated into phospholipid fractions. These *in vitro* effects were prevented by culturing cells in the presence of excess choline (Lehman-McKeeman and Gamsky, 1999).

4. DEA caused morphological transformation in Syrian hamster embryo (SHE) cell transformation assay. However, this response was prevented when SHE cells were cultured in a medium containing excess choline (Lehman-McKeeman and Gamsky, 2000).

5. DNA synthesis was increased in mouse and rat, but not human, hepatocytes incubated with DEA. Incubation of mouse and rat, but not human, hepatocytes in medium containing reduced choline increased DNA synthesis. Mouse and rat

hepatocytes incubated in medium with excess choline reduced DEA-induced DNA synthesis to control levels or below (Kamendulis and Klaunig, 2005).

6. DNA hypomethylation in GC-rich promotor regions observed in primary mouse hepatocytes which have been treated with DEA are similar to those caused by choline-deficient medium (Bachman *et al.*, 2005).

In situ formation of N-nitrosodiethanolamine

DEA is a secondary amine and may react with a nitrosating agent under certain conditions to form N-nitrosodiethanolamine. This nitrosoamine has been shown to be mutagenic *in vitro* and cause liver tumors in rats and doses of 2 mg/kg-day and higher (ECETOC, 1990). Rats given high, often toxic, oral bolus doses of DEA and nitrite have shown or inferred to produce N-nitrosodiethanolamine (Preussman *et al.*, 1981; Yamamoto *et al.*, 1995). Studies by Stott *et al.* (2000) showed, however, that mimicking the dosing conditions in the NTP study (160 mg/kg DEA dermally) and drinking water supplemented with 170 ppm sodium nitrite to favor nitrosation did not result in N-nitrosodiethanolamine formation in the gastric contents, blood or urine of mice. The findings of Stott *et al.* (2000) suggest that the mouse liver tumors observed in the NTP bioassay were unlikely due to *in situ* nitrosamine formation.

Relevance to Humans

There are marked species differences in susceptibility to choline deficiency, with rats and mice being far more susceptible than other species including humans (Zeisel and Blusztajn, 1994). Rats and mice have a higher dietary choline requirement than humans in large part because rodents oxidize choline more rapidly than humans (Sidransky and Farber 1960). DEA was carcinogenic in mice, but not in rats, in the NTP dermal carcinogenicity studies. The fact that DEA was not carcinogenic to rats, a species highly susceptible to choline deficiency, should be an important consideration in the overall evaluation of human cancer risk. DEA is less readily absorbed across rat skin than mouse skin, and the resulting blood and tissue concentrations of DEA are at least three-times lower in rats than in mice at similar dosages (Mathews *et al.*, 1997). Lehman-McKeeman *et al.*, (2002) determined the NOAEL for DEA-induced choline deficiency in mice (based on phosphocholine concentrations) to be 10 mg/kg-day. Thus, there is a critical concentration of DEA that must be reached in order to affect choline homeostatis. In the rats, the lack of a carcinogenic response suggests that it is unlikely that exposure to DEA reached this concentration or that rats are not as susceptible as mice to the effects of DEA on hepatic choline metabolism. Overall, the results suggest that the hepatocarcinogenic effects of DEA in mice are not predictive of similar susceptibility in other laboratory animals or humans. As noted by ECHA, “mechanistic research specifically on DEA indicates that, to the extent DEA can potentially induce tumours in mice, it does so by a mechanism that is not relevant to humans. Therefore, based on the available data, DEA is not considered carcinogenic for humans.”

I. Reproductive Toxicity

No specific reproductive toxicity studies have been conducted on diethanolamine by any route of exposure.

In the NTP 13-week drinking water study, F344 rats were given 0, 160 (females only), 320, 630, 1,250, 2,500 or 5,000 ppm (males only) diethanolamine. All high-dose males and 3/10 of the 2,500 ppm males showed testicular degeneration; male rats in the higher dose groups also had atrophy of the seminal vesicles and prostate glands. Testis and epididymal weights in the ≥1,250 ppm males were decreased and were associated microscopically with degeneration of seminiferous epithelium, as well as hypospermia and reduced sperm motility in the ≥2,500 ppm males. The NOAEL for reproductive effects in males was 630 ppm (corresponding to 48 mg/kg-day). There were no effects noted in the female reproductive organs (NTP 1992; Melnick *et al.* 1994b).

In a 90-day inhalation study, some of the male Wistar rats exposed whole-body to 400 mg/m^3 showed diffuse testicular atrophy accompanied by oligozoospermia in the epididymides, and slight prostate atrophy (ECHA).

J. Developmental Toxicity

Oral

A Chernoff-Kavlok screen was conducted on diethanolamine. Initially, four female CD-1 mice were given by oral gavage 0, 200, 380, 720, 1,370, 2,605, and 2,605 mg/kg diethanolamine during GD 6-15; a subsequent study was conducted which consisted of dosing 50 female CD-1 mice with 450 mg/kg during GD 6-15. Mortality was seen at ≥720 mg/kg, with 100% mortality in the ≥1,370 mg/kg groups. Dams dosed with ≥200 mg/kg showed clinical signs of intoxication. There was no mortality in the 450 mg/kg dams; nor was there any effect on litter size and pup birth weight, but the number of viable litters, the percent of pup survival, and pup weight gain were reduced (York *et al.* 1988). Kl. score = 2]

Female SD rats were dosed by oral gavage with 0, 50, 125, 200, 250, or 300 mg/kg diethanolamine from GD 6-19. All dams in the 300 mg/kg group had to be killed early due to excessive toxicity. At 200 and 250 mg/kg, the dams exhibited either morbidity or died. Water intake was affected early in the gestation period in the 125 and 250 mg/kg dams; it was comparable to controls after GD 12. Reduced maternal body weight and weight change, as well as food intake, were seen in the ≥200 mg/kg dose groups. The ≥125 mg/kg dams had increased absolute kidney weights on postnatal day (PND) 21. There were no maternal effects in the 50 mg/kg dams. There was postimplantation deaths at ≥200 mg/kg on PND 0 and increased early postnatal mortality (PND 0-4) in the ≥125 mg/kg dose groups. Pup body weight was reduced at ≥200 mg/kg, with females affected more than males. Pup body weight gain was predominantly reduced during the early postnatal period. There were statistically significant differences at the end of the

lactational period, which were flawed by the low number of animals. The NOAEL for maternal and postnatal developmental (screening) toxicity was 50 mg/kg-day (Price *et al.* 2005). [Kl. score = 2]

Inhalation

Pregnant female Wistar rats were exposed by inhalation to 0, 10, 50, or 200 mg/m^3 diethanolamine 6 hours/day on GD 6 to 15. Maternal toxicity was seen at 200 mg/m^3; there were vaginal hemorrhages in 8/21 pregnant rats on GD 14. There was also a markedly increased number of fetuses with skeletal variations (mainly cervical ribs) in the 200 mg/m^3 exposed group. The NOAEC for maternal and developmental toxicity is 200 mg/m^3 (ECHA). [Kl. score = 1]

Dermal

Pregnant female SD rats were given dermal applications of 0, 150, 500, or 1,500 mg/kg diethanolamine from GD 6 to 15. There was a dosing discrepancy and mid-dose was adjusted from 500 to 380 mg/kg. There was moderate skin irritation in the 380 mg/kg group, and severe skin irritation in the 1,500 mg/kg group. Body weight gain was lower in the 1,500 mg/kg group, and absolute and relative kidney weights were increased in the ≥380 mg/kg group All treated groups exhibited hematological effects that included anemia, abnormal red cell morphology (poikilocytosis, anisocytosis, polychromasia), and decreased platelet count. The 1,500 mg/kg group also had increased lymphocytes and total leukocytes. There were no treatment-related effects on body weight or incidences of malformations/abnormalities. In the 1,500 mg/kg litters, there were increased incidences of six skeletal variations involving the axial skeleton and distal appendages. The skeletal variations included poor ossification in the parietal bones; cervical centrum #5 and thoracic centrum #10; lack of ossification in all proximal hindlimb phalanges and some forelimb metacarpals; and callused ribs. The NOAELs for maternal and developmental toxicity are 150 and 380 mg/kg-day (Marty et al., 1999). [Kl. score = 2]

Pregnant female New Zealand rabbits were given dermal applications of 0, 35, 100, or 350 mg/kg diethanolamine on GD 6 to 18. At 350 mg/kg, maternal toxicity consisted of marked skin irritation, reduced feed consumption, and color changes in the kidneys. There were no hematologic changes. Body weight gain was reduced in the 100 mg/kg group. There was no evidence of developmental toxicity at any dose level. The NOAELs for maternal and developmental toxicity are 35 and 350 mg/kg-day (Marty et al., 1999). [Kl. score = 2]

K. Immunotoxicity

Female F344 rats were given oral gavage doses of 0, 50, 100, or 200 mg/kg diethanolamine for 14 days. Body weights and/or body weight changes were significantly decreased in the ≥100 mg/kg dose groups; liver and kidney weights were increased in a dose-dependent manner. A dose-dependent increase in urea nitrogen

was seen in all dose groups. Erythrocytes, hematocrit, hemoglobin and reticulocytes were dose-dependently decreased. The reticulocytes were the most sensitive erythroid parameter, which was decreased at all dose levels. Besides an increase in the proliferative response to allogenic cells (MLR), several immune functional assays were decreased including the natural killer cell response and the cytotoxicity of resident macrophages. Conversely, the cytotoxicity of peptone-elicited macrophages was increased. The LOAEL was 50 mg/kg-day based on a significant decrease in reticulocyte number and increase in urea nitrogen (Munson *et al.* 1992a). [Kl. score = 2]

Female B6C3F_1 mice were given oral gavage doses of 0, 100, 300, or 600 mg/kg diethanolamine for 14 days. There was no effect of body weights. The liver weights were increased and red blood cell count parameter were dose-dependently decreased at all dose levels. Diethanolamine treatment increased the number of B-cells, decreased the number of CD4+CD8- (18%) T-cell subsets. A dose-dependent decrease in the antibody-forming cell response to sheep erythrocytes at the high-dose was seen, as well as a decrease in the cytotoxic T-cell response at the highest effector/target ratio. The cytotoxicity of resident macrophages was decreased, but the cytotoxicity of resident macrophages stimulated with gamma interferon was not affected nor the cytotoxicity of peptone-elicited macrophages with or without stimulation. Among the three host resistance studies, a decrease in host resistance was observed to *Streptococcus pneumonia* and in the B16F10 melanoma tumor model. The LOAEL for this study was considered to be 100 mg/kg-day based on significantly reduced cytotoxic T lymphocytes (CTL) activity, an increase in tumor burden following challenge with the B16F10 melanoma tumor and a clear decrease in red blood cell parameter at the lowest dose (Munson *et al.* 1992b). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diethanolamine follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

In a 13-week study conducted by the National Toxicology Program, F344 rats were given diethanolamine in their drinking water for 13 weeks. The doses were 0, 25, 48, 97, 2,202, or 436 mg/kg-day for males; and 0, 14, 32, 57, 124, or 242 mg/kg-day for females. The most sensitive endpoints were the microcytic anemia in both sexes and kidney effects in females (weight, nephrotoxicity) and males (weight). The LOAELs were 25 and 14 mg/kg-day) for males and females, respectively (NTP 1992; Melnick et al., 1994a).

In a 13-week study conducted by the National Toxicology Program, B6C3F_1 mice were given diethanolamine in their drinking water for 13 weeks. The doses were 0, 104, 178, 442, 807, or 1,674 mg/kg-day for males; and 0, 142, 347, 884, 1,154, or 1,128 mg/kg-day for females. The most sensitive endpoint was the increase in liver weights with the corresponding histopathological changes. The LOAELs were 104 and 142 mg/kg-day in males and females, respectively (NTP, 1992; Melnick *et al.*, 1992b).

The lowest NOAEL of 14 mg/kg-day from the rat 13-week drinking water study will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 10
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

[maximum UF = 3,000]

Oral RfD = 14/3,000 = <u>0.005 mg/kg-day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.005 x 70 x 0.1)/2 = <u>0.02 mg/L</u>

B. Cancer

Diethanolamine was not carcinogenic to rats in the two-year NTP dermal bioassay; but, in the mice, there was an increased incidence of liver tumors in males and females and kidney tumors in males (NTP, 1999). As discussed above, the mouse liver tumors from DEA exposure are unlikely to be predictive of the carcinogenic risk to humans based on choline deficiency as a mechanism of carcinogenesis. No mode-of-action has been proposed for the kidney tumors in male mice.

NICNAS conducted a human health tier III assessment on diethanolamine (NICNAS). Regarding the classification for carcinogenicity, NICNAS concluded that "[t]he data on the mode of action are insufficient to conclude that diethanolamine-induced tumours in mice are relevant for humans and, therefore, based on the available information, diethanolamine is not classified for carcinogenicity."

Thus, a cancer reference value for diethanolamine was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diethanolamine does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Diethanolamine exhibits moderate acute toxicity to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies on diethanolamine.

Table 3: Acute Aquatic Toxicity Studies on Diethanolamine

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LC_{50}	460	2	ECHA
Pimephales promelas	96-h LC_{50}	1,460*	2	Mayes et al. (1983)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-h LC_{50}	1,664	2	ECHA
Lepomis macrochirus	48-h LC_{50}	1,850	2	Turnbull et al. (1954)
Carassius auratus	24-h LC_{50}	>5,000 (neutralised) 800 (non-neutralised)	2	Bridlé et al. (1979)
Ceriodaphnia dubia	48-h EC_{50}	30.1 (24°C) 89.9 (20°C)	2	Cowgill et al. (1985)
Daphnia magna	48-h EC_{50}	55	2	LeBlanc (1980)
Daphnia magna	48-h EC_{50}	171	2	Zurita et al. (2005)
Pseudokirchneriella subcapitata	72-h EC_{50} (growth rate)	9.5 (Test 1) 19 (Test 2)	2	ECHA
Desmodesmus subspicatus	72-h EC_{50}	14.9 (growth rate) 6.2 (biomass)	2	ECHA
Desmodesmus subspicatus	72-h EC_{50}	107.3 (growth rate) 74.5 (biomass)	2	ECHA
Chorella vulgaris	72-h EC_{50}	778 (growth rate)	2	ECHA

*Geometric mean of 96-h LC_{50} values of fry, juvenile, and subadult fish. Not neutralized.

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies on diethanolamine.

Table 4: Chronic Aquatic Toxicity Studies on Diethanolamine

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Daphnia magna	EC_{10} NOEC	1.05 0.76	1	ECHA
Pseudokirchneriella subcapitata	EC_{10} (growth rate)	1.4 (Test 1) 1.1 (Test 2)	2	ECHA
Desmodesmus subspicatus	EC_{10} (neutralized)	2.4 (growth rate) 2.0 (biomass)	2	ECHA
Desmodesmus subspicatus	EC_{10} (non-neutralized)	85.7 (growth rate) 41.3 (biomass)	2	ECHA
Pseudokirchneriella subcapitata	7-d NOEC	10	2	ECHA

C. Terrestrial Toxicity

In an earthworm (*Eisenia Andrei, Eisenia fetida*, or *Lumbricus terrestris*) study, the 35-day LC_{50} was 4,141 mg/kg soil dry weight (mortality); the 63-day EC_{50} was 776 mg/kg soil dry weight (reproduction); and the 63-day EC_{25} was 171 mg/kg soil dry weight (reproduction) (ECHA). [Kl. score = 2]

In a springtails (*Folsomia candida*) study, the 28-day LC_{50} was 8,301 mg/kg soil dry weight (mortality); the 28-day EC_{50} was 4,205 mg/kg soil dry weight (reproduction); and the 28-day EC_{25} was 2,102 mg/kg soil dry weight (reproduction) (ECHA). [Kl. score = 2]

D. Calculation of PNEC

The PNEC calculations for diethanolamine follow the methodology discussed in DEWHA (2009).

<u>PNEC water</u>
Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (460 mg/L), *Daphnia* (30.1 mg/L), and algae (9.5 mg/L). Results from chronic studies are also available for two trophic levels, with the lowest EC_{10} value being 1.1 mg/L for *Daphnia* and algae. On the basis that the data consists of short-term results from three trophic levels and long-term results from three trophic levels, an

assessment factor of 50 has been applied to the lowest reported EC_{10} of 1.1 mg/L for algae. The $PNEC_{water}$ is 0.02 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.016 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.99/1280) \times 1000 \times 0.02$
$= 0.016$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.4/1000 \times 2400]$
$= 0.99$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 10 \times 0.04$
$= 0.4$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for diethanolamine (as the charged molecule) was calculated to be 10 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

Experimental results are available for chronic toxicity on two trophic levels. Although $E(L)C_{50}$ values are available from these studies, there are no EC_{10} or NOEC values. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.027 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.2/1500) \times 1000 \times 0.02$
$= 0.027$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 10 \times 0.02$
$= 0.2$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethanolamine (as the charged molecule) was calculated to be 10 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diethanolamine is readily biodegradable; thus, it does not meet the screening criteria for persistence.

The estimated BCF value for diethanolamine calculated from a QSAR model is 2.3; thus, it does not meet the criteria for bioaccumulation.

The EC_{10} or NOEC values from the chronic aquatic toxicity studies on diethanolamine are >0.1 mg/L. Thus, diethanolamine does not meet the screening criteria for toxicity. In a mouse dermal carcinogenicity study, there was an increased incidence of liver tumors in males and females and kidney tumors in males. However, both ECHA and NICNAS has concluded that "[t]he data on the mode of action are insufficient to conclude that diethanolamine-induced tumours in mice are relevant for humans and, therefore, based on the available information, diethanolamine is not classified for carcinogenicity." Thus, diethanolamine does not meet the criteria for toxicity.

Therefore, diethanolamine is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]
Skin Irritant Category 2
Eye Damage Category 1
STOT RE Category 2 [Target organs: liver, blood, kidney]

[Aquatic Acute Category 2]

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
Remove contaminated clothing. Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Give artificial respiration if victim is not breathing. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: nitrogen oxides, carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
For large amounts: dike spillage and pump off product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling
Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for diethanolamine.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection:
Use respiratory protection in case of vapor or aerosol release.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diethanolamine is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Bachman, A.N., Kamendulis, L.M., and Goodman, J.I. (2006). Diethanolamine and phenobarbital produce an altered pattern of methylation in GC-rich regions of DNA in B6C3F1 mouse hepatocytes similar to that resulting from choline deficiency. Toxicol. Sci. 90: 317-325.

Barbee, S.J., and Hartung, R. (1979). The effect of diethanolamine on hepatic and renal phospholipid metabolism in the rat. Toxicol. Appl. Pharmacol. 47: 421–430.

Bridié AL, Wolff CJM, and Winter M (1979). The acute toxicity of some petrochemicals to goldfish. Water Research 13, 623-626.

Counts, S.L., Sarmiento, J.I., Harison, M.L., Downing, J.C., McClain, R.M., and Goodman, J.I. (1996). Cell proliferation and global methylation status after phenobarbital and/or choline-devoid, methionine-deficient diet administration. Carcinogenesis 17: 1251-1257.

Cowgill, U.M., Takahashi, I.T., and Applegath, S.L. (1985). A comparison of the effect of four benchmark chemicals on *Daphnia magna* and *Ceriodaphnia dubia-affinis* tested at two different temperatures. Environ. Toxicol. Chem. 4: 415-422.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Dimitrov, S., Dimitrova, N., Parkerton, T., Comber, M., Bonnell, M., and Mekenyan, O. (2005). SAR and QSAR in Environ. Res. 16: 1-24.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Dean, B.J., Brooks, T.M., Hodson-Walker, G., and Hutson, D.H. (1985). Genetic toxicology testing of 41 industrial chemicals. Mutat. Res. 153: 57-77.

ECETOC (1990). Human exposure to N-nitrosamines, their effects, and a risk assessment for N-nitrosodiethanolamine in personal care products. Technical Report no. 41, European Chemical Industry Ecology and Toxicology Center, Brussels, Belgium.

Franco, A., and Trapp, S. (2008). Estimation of the soil-water partition coefficient normalized to organic carbon for ionizable organic chemicals. Environ. Toxicol. Chem. 27: 1995-2004.

Franco, A., Fu, W., and Trapp, S. (2009). Influence of the soil on the sorption of ionizable chemicals: modeling advances. Environ. Toxicol. Chem. 28: 468-464.

Fullerton, F.R., Hoover, K., Mikoi, Y.B., Creasia, D.A., and Poirier, L.A. (1990). The inhibition by methionine and choline of liver carcinoma formation in male C3H mice dosed with diethylnitrosamine and fed phenobarbital. Carcinogenesis 11: 1301-1305.

Garner, A.O., Rossbacher, R., Kaufmann, W., and van Ravenzwaay, B. (2008). The inhalation toxicity of di- and triethanolamine upon repeated exposure. Food. Chem. Toxicol. 46: 2173-2183.

Haworth, S., Lawlor, T., Mortelmans, K., Speck, W., and Zeiger, E. (1983). Salmonella mutagenicity test results for 250 chemicals. Environ. Mutagen. 5 (Suppl. 1), 3-142.

Kamendulis, L.M., and Klaunig, J.E. (2005). Species differences in the induction of hepatocellular DNA synthesis by diethanolamine. Toxicol. Sci. 87: 328-336.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

LeBlanc, G.A. (1980). Acute toxicity of priority pollutants to water flea (*Daphnia magna*). Bull. Environ. Contam. Toxicol. 24: 684-691.

Lehman-McKeeman, L.D., and Gamsky, E.A. (1999). Diethanolamine inhibits choline uptake and phosphatidylcholine synthesis in Chinese Hamster Ovary cells. Biochem. Biophys. Res. Commun. 262: 600-604.

Lehman-McKeeman, L.D., and Gamsky, E.A. (2000). Choline supplementation inhibits diethanolamine-induced morphological transformation in Syrian hamster embryo cells: evidence for a carcinogenic mechanism. Toxicol. Sci 55: 303-10.

Lehman-McKeeman, L.D., Gamsky, E.A., Hicks, S.M., Vassallo, J.D., Mar, M.-H., and Zeisel, S.H. (2002). Diethanolamine induces hepatic choline deficiency in mice. Toxicol. Sci. 67: 38-45.

Loveday, K.S., Lug, M.H., Resnick, M.A., Anderson, B.E., and Zeiger, E. (1989). Chromosome aberration and sister chromatid exchange tests in Chinese hamster ovary cells in vitro. II. Results with 20 chemicals. Environ. Mol. Mutagen., 13. 60-94.

Marty, M.S., Neeper-Bradley, T.L., and Neptun, D.A. (1999). Developmental toxicity of diethanolamine applied cutaneously to CD rats and New Zealand rabbits. Regul. Toxicol. Pharmacol. 30: 169-181.

Mathews, J.M., Gamer, C.R., and Matthews, R.B. (1995). Metabolism, bioaccumulation, and incorporation of diethanolamine into phospholipids, Chem. Res. Toxicol. 18: 625-633.

Mathews, J.M., Gamer, C.R., Black, S.L., and Matthews, R.B. (1997). Diethanolamine absorption, metabolism and disposition in rat and mouse following oral, intravenous and dermal administration. Xenobiotica 27: 733-746.

Mayes, M.A., Alexander, H.C., and Dill, D.C. (1983). Study to assess the influence of age on the response of fathead minnows in static acute toxicity tests. Bull. Environ. Contam. Toxicol. 31: 139-147.

Melnick, R.L., Mahler, J., Bucher, J.R., Thompson, M., Hejtmancik, M., Ryan, M.J., and Mezza, L.E. (1994a). Toxicity of diethanolamine. 1. Drinking water and topical application exposures in F344 rats. J. Appl. Toxicol. 14: 1-9.

Melnick, R.L., Mahler, J., Bucher, J.R., Hejtmancik, M., Singer, A., and Persing R.L. (1994b). Toxicity of diethanolamine. 2. Drinking water and topical application exposures in B6C3F1 mice. J. Appl. Toxicol. 14: 11-19.

Mendrala, A.L., Waechter, J.M., Bormett, G.A., Bartels, M.J., and Stott, W.T. (2001). The pharmacokinetics of diethanolamine in Sprague-Dawley rats following intravenous administration. Food Chem. Toxicol. 39: 931-939.

Munson, A.E., White, K.L., and McCay, J.A. (1992). Immunotoxicity of diethanolamine in female Fischer 344 rats. Report to National Toxicology Program. Richmond VA, USA: Virginia Commonwealth University, Medical College of Virginia, Immunotoxicology Program; cited in OECD 2007.

Munson, A.E., White, K.L., and McCay, J.A .(1992). Immunotoxicity of diethanolamine in female B6C3F1 mice. Report to National Toxicology Program. Richmond VA, USA: Virginia Commonwealth University, Medical College of Virginia, Immunotoxicology Program; cited in OECD 2007.

Myhr, B.C., Bowers, L.R., and Caspary, W.J. (1986). Results from the testing of coded chemicals in the L5178Y TK+/- mouse lymphoma mutagenesis assay. Environ. Mutagen. 7(Suppl. 3): 58 [abstract].

National Toxicology Program [NTP] (1992). Toxicity Studies of Diethanolamine (CAS No. 111-42-2) Administered Topically and in Drinking Water to F344/N Rats and B6C3F1 Mice. Tech. Rep. Ser. No. 20, NIH Publication No. 92-3343, Department of Health and Human Services, Research Triangle Park, NC.

National Toxicology Program [NTP] (1999). Toxicology and Carcinogenesis Studies of Diethanolamine (CAS No. 111-42-2) in F344/N Rats and B6C3F1 Mice (Dermal Studies). Tech. Rep. Ser. No. 478, NIH Publ. No. 99-3968, Research Triangle, NC.

Newberne, P.M., deCamagro, J.L.V., and Clark, A.J. (1982). Choline deficiency, partial hepatectomy, and liver tumors in rats and mice. Toxicol. Pathol. 10: 95-106.

Newberne, P.M., Suphiphat, V., Lockniskar, M., and de Carmargo, J.L.V. (1990). Inhibition of hepatocarcinogenesis in mice by dietary methyl donors methionine and choline. Nutr. Cancer 14: 175-181.

NICNAS. Human Health Tier III assessment for Ethanol, 2,2'-iminobis-. Last update 19 April 2017. Available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-iii-human-health/ethanol,-2,2-iminobis-.

OECD (2007). SIDS Initial Assessment Report for SIAM 24: 2,2'-Iminodiethanol (CAS No. 111-42-2).

Preussmann, R., Speigelhalder, B., Eisenbrand, G., Wurtele, G., Hofmann, I. (1981). Urinary excretion of N-nitrosodiethanolamine in rats following its epicutaneous and intratracheal administration and its formation in vivo following skin applications of diethanolamine. Cancer Lett. 13: 227-231.

Price, C.J., Marr, M.C., Myers, C.M., and Jahnke, G.D. (2005). Postnatal developmental of rat pups after maternal exposure to Diethanolamine. Birth Defects Res. (Part B) 74: 243-254.

Rogers, A.E. (1995). Methyl donors in the diet and response to chemical carcinogens. Am. J. Clin. Nutr. 61(Suppl 3): 659S-665S.

Sidransky, H., and Farber, E. (1960). Liver choline oxidase activity in man and in several species of animals. Biochim. Biophys. Acta 1348: 142-150.

Stott, W.T., Bartels, M.J., Brzak, K.A., Mar, M.-H., Markham, D.A., Thornton, C.M., and Zeisel, S.H. (2000). Potential mechanisms of tumorigenic action of diethanolamine in mice. Toxicol. Lett. 114: 67–75.

Turnbull, H., DeMann, J.G., and Weston, R.F. (1954). Toxicity of various refinery materials to fresh water fish. Ind. Eng. Chem. 46: 324-333.

Witt, K.L., Knapton, A., Wehr, C.M., Hook, G.J., Mirsalis, J., Shelby, M.D., MacGregor, J.T. (2000). Micronucleated erythrocyte frequency in peripheral blood of B6C3F1 mice from short-term, prechronic and chronic studies of the NTP carcinogenesis bioassay program, Environmental Mol. Mutagen. 36: 163-194.

Yamamoto, K., Tsutsumi, M., Kobayashi, E., Endoh, T., Noguchi, O., Okajima, E., Denda, A., Mori, Y., and Konishi, Y. (1995). Initiation of hepatocarcinogenesis by endogenously formed N-nitroso-bis(2- hydroxypropyl)amine, N-nitrosodiethanolamine and N-nitroso-2,6- dimethylmorpholine in rats. Carcinogenesis 16: 2633–2636.

York, R.G., Barnwell, P.L., Pierrera, M., Schuler, R.L., and Hardin, B.D. (1988). Evaluation of twelve chemicals in a preliminary developmental toxicity test. Teratol. 37: 503-504.

Zeisel, S.H. (1996). Choline: A nutrient that is involved in the regulation of cell proliferation, cell death and transformation. Adv. Exp. Med. Biol. 399: 131-141.

Zeisel, S.H., and Blusztajn, J.K. (1994). Choline and human studies. Annual Rev. Nutr. 14: 269-296.

Zurita, J.L., Repetto, G., Jos. A., del Peso, A., Salguero, M., López-Artíguez, A., Olano, D., and Cameán, A. (2005). Ecotoxicological evaluation of diethanolamine using a battery of microbiotests. Toxicol. In Vitro 19: 879-886.

DIETHYLENE GLYCOL

This dossier on diethylene glycol presents the most critical studies pertinent to the risk assessment of diethylene glycol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-(2-hydroxyethoxy)ethan-1-ol

CAS RN: 111-46-6

Molecular formula: $C_4H_{10}O_3$ or $(CH_2CH_2OH)_2O$

Molecular weight: 106.12 g/mol

Synonyms: Diethylene glycol; 2,2'-oxydiethanol; diglycol; bis(2-hydroxyethyl) ether; 2-hydroxyethyl ether; 2,2'-oxybisethanol; 2-(2-hydroxyethoxy)ethanol; ethanol, 2,2'-oxybis-; 2-(2-hydroxyethoxy)ethan-1-ol; glycol ethyl ether; ethylene diglycol

SMILES: C(COCCO)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	A colourless viscous liquid	2	ECHA
Melting point	-6.5°C @ 101.3 kPa	2	ECHA
Boiling point	244.9°C @ 101.3 kPa	2	ECHA
Density	1,118 kg/m^3 @ 20°C	2	ECHA
Vapour pressure	0.008 hPa @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	-1.98 (calculated)	2	ECHA
Water solubility	1,000 g/L @ 20°C	2	ECHA
Flash point	138°C	2	ECHA
Auto flammability	372°C	2	ECHA
Viscosity	30 mPa s (dynamic) @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is readily biodegradable, is unlikely to bioaccumulate, nor is it likely to adsorb or desorb to soil or sediment to a great extent.

B. Biodegradation

Diethylene glycol is readily biodegradable. In an OECD 301B test, there was 70-80% and 90-100% degradation after 28 days, as determined by CO_2 evolution and DOC removal respectively (ECHA) [KI score = 2].

In an OECD 301A test, there was 90-100% degradation after 28 days, although the 10-day window was missed (ECHA) [KI score = 1]. In a modified MITI I test (OECD 301C), there was up to 92% degradation after 28 days (ECHA) [KI score = 2].

C. Environmental Distribution

No experimental data are available for diethylene glycol. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} value from the molecular connectivity index (MCI) and log K_{oc} are 1 and -0.08 L/kg, respectively (ECHA) [KI Score = 2]. Based on these K_{oc} values, if released to soil, diethylene glycol is expected to not adsorb to soil and have a very high mobility. If released to water, based on the K_{oc} value and its water solubility, it is also not expected to adsorb to suspended solids and sediment.

D. Bioaccumulation

The calculated log K_{ow} for diethylene glycol is -1.98 (Verschueren, 1983). Diethylene glycol has low potential to bioaccumulate. In a 3-day bioaccumulation fish study with Leuciscus idus melanotus, the BCF was determined to be 100 (Freitag et al., 1985) [KI score = 2].

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance exhibits low oral acute toxicity. It is not a significant skin or eye irritant, nor is it considered to be a skin sensitiser. No dermal or inhalation repeat dose studies were available but oral repeat does studies suggest moderate urinary dysfunction with oxalate formation in rats. The substance is not genotoxic, carcinogenic nor developmentally toxic.

B. Acute Toxicity

The oral LD_{50} in rats is 19,600 mg/kg (Lenk et al., 1989; ECHA) [KI score = 2]; and 16,500 mg/kg (Laug et al., 1939; ECHA) [KI score = 2].

No deaths were reported in rats exposed to a saturated vapour for 6 hours (OECD, 2007) [KI score = 2]. No deaths were also reported in male and female Aplk:APfSD (Wistar-derived) rats exposed to 5,080 mg/m^3 diethylene glycol aerosol (MMAD = 2.83 µm, GSD = 2.05) for 4 hours (OECD, 2007) [KI score = 2].

The dermal LD_{50} in rabbits was reported to be 12,500 mg/kg (OECD, 2007) [KI score = 2]. The dermal LD_{50} in rabbits was reported to be 13,300 mg/kg (ECHA) [KI score = 4].

C. Irritation

When applied to the skin of rabbits for 24 hours under occlusive conditions, diethylene glycol was essentially non-irritating with a PII score of 0.04 (Guillot et al., 1982, ECHA) [KI score = 2]. In a human repeated irritation patch test, diethylene glycol was minimally irritating to the skin (OECD, 2007) [KI score = 2].

Diethylene glycol was not considered a skin irritant in an *in vitro* reconstructed human epidermis test (ECHA) [KI score = 1].

Instillation of 0.1 mL diethylene glycol into the eyes of rabbits produced minor, transient irritation; no corneal lesions were observed (OECD, 2007) [KI score = 2]. When instilled into the eyes of rabbits, the ocular irritancy was 11.67 based on a modified Kay Calandra scale of 0 to 110 (Guillot et al., 1982, ECHA) [KI score = 2].

D. Sensitisation

Diethylene glycol was not a skin sensitiser to guinea pigs in a maximisation test (OECD, 2007; ECHA) [KI score = 1]. Diethylene glycol was not a skin sensitiser in a human repeat irritation patch test (OECD, 2007; ECHA) [KI score = 4].

E. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their diet 0, 0.085, 0.17, 0.4 and 2.0% diethylene glycol for 225 days. The corresponding average daily intakes were 0, 51, 105, 234 and 1,194 mg/kg/day for males; and 0, 64, 126, 292 and 1462 mg/kg/day for females. In the 0.4% and 2% groups, there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The only finding in the 0.17% group was a 13.2% increase in urinary oxalate excretion in males; no effects were observed in the 0.085% group. The NOAEL and NOEL for this study is considered to be 0.17% (approximately 105 mg/kg/day) and 0.085% (approximately 51 mg/kg/day), respectively (ECHA) [KI score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on diethylene glycol are shown in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Diethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	OECD (2007), ECHA
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	2	OECD (2007), ECHA
Sister chromatid exchange (CHO cells)	-	-	2	OECD (2007), ECHA

*+, positive; -, negative

In Vivo Studies

Micronuclei were not increased in the bone marrow of NMRI mice given a single intraperitoneal injection of 0, 500, 1,000 or 2,000 mg/kg diethylene glycol (ECHA) [KI score = 1].

G. Carcinogenicity

Oral

Male and female F344 rats were given in their drinking water 0, 1.25 or 2.5% diethylene glycol (97% purity) for two years. The daily intake was estimated to be 0, 1,210 and 2,630 mg/kg/day for males; and 0, 1,160 and 2,550 mg/kg/day for females. Mortality was increased in the 2.5% males; drinking water consumption was increased in the 2.5% males and females. There were no significant differences in the incidence of tumours between treated and control animals (Hiasa et al., 1990; ECHA) [KI score = 2].

Male Osborne-Mendel rats were given in their feed 0, 1, 2 or 4% diethylene glycol for two years. During the first 26 weeks of the study, weight gain was significantly reduced at all dose levels. After the first year, the growth of rats fed the 4% diets was significantly reduced relative to the controls. There were no significant differences in food consumption at any treatment level. Mortality in rats fed the 4% diet was significantly higher than the control group; all animals were found dead before the end of the study (most dying during the last 12 months), compared with 7/12 control deaths. The incidence of bladder stones and bladder tumours increased with diethylene glycol exposure, with 0, 0, 6 and 5 bladder tumours observed in the control, 1, 2 and 4% DEG groups, respectively. Bladder stones were observed in 0, 2, 7 and 11 rats in the control, 1, 2 and 4% groups, respectively. In all but one case, bladder stones were present when bladder tumours were observed, suggesting that chronic irritation was a factor in the production of bladder tumours. The severity and incidence of signs of kidney damage (hydronephrosis, hydroureter, focal tubular atrophy, hyalin cast formation, glomerular atrophy) increased in a treatment-related manner, with gross kidney lesions observed in 1/12, 3/12 and 8/12 of the rats in the low-, mid- and high-dose groups, respectively. Liver damage observed histologically also increased with the level of diethylene glycol exposure. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Fitzhugh and Nelson, 1946) [KI score = 3].

Male and female rats were given in their feed 0, 2 or 4% diethylene glycol (containing 0.031% ethylene glycol) for two years. Rats were either just weaned, 2 months old or 12 months old at the initiation of the exposure. The dietary concentration of diethylene glycol was adjusted for the food consumption and body weight of each group. For 4% diet, the dosage in weanlings was 5,400 mg/kg/day for the first 28 days, approximately 3,700 mg/kg/day during the next two-week period, gradually declined to about 2,000 mg/kg/day over the next three months and remained at that level for the rest of the study. A study average of 2,300 mg/kg/day for weanlings fed 4% in the diet was calculated from data provided by the authors. None of the 12-month old male rats included in the study survived, whereas all the females in that group survived to termination of the study. Although weanling rats developed more bladder stones than the other groups, the difference was insignificant. The yearling rats developed their bladder stones somewhat earlier. The yearling rats in the 4% groups had the highest stone formation (8 out of 20 rats) and had the only bladder tumour in this dose group; the rat with the bladder tumour also had bladder stones. No bladder stones or tumours were observed in rats of any age in the control or in the 2% groups. The bladder tumours associated with the stones were considered to be the result of mechanical irritation, and diethylene glycol was not considered to be a primary rat carcinogen. The LOAEL and NOAEL for this study were dietary concentrations of 4% and 2% (approximately 2,300 and 1,200 mg/kg), respectively. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Weil et al., 1965) [Kl score = 3].

H. Reproductive Toxicity

In a two-generation study, male and female rats were dosed by oral gavage with 1 mL/100 g body weight of a 20% aqueous solution of diethylene glycol (approximately 2 mL/kg/day) for 8 weeks. A control group was given daily oral gavage doses of 1 mL/100 g body weight distilled water. Five of the treated females were dosed with diethylene glycol until parturition, the other five until the pups were weaned. Treatment of the P-generation with diethylene glycol for 12 weeks did not impair reproduction. The test animals and the controls became pregnant at almost the same time, litter size averaged 8-10 young, and the young exhibited similar, uniform development. Growth and onset of oestrus were not affected by treatment. The endocrine glands investigated showed no differences from the controls with regard to weight and fine structure. The receptiveness and litter size of the untreated F1 generation were the same as those of the P-generation, and the F2 generation was normal with regard to weight gain, onset of sexual maturity and weight as well as histology of the organs examined. The NOAEL for this study was calculated to be 2,200 mg/kg/day (Wegener, 1953; ECHA) [Kl score = 2].

A continuous breeding protocol (RACB) was used to study the reproductive toxicity of diethylene glycol in mice. Male and female CD-1 mice were administered in their drinking water 0, 0.35, 1.75 or 3.5% diethylene glycol. Mice were exposed for 7 days prior to mating, 98 days during cohabitation of breeding pairs and a further 23 days after segregation of each pair.

Breeding study: The mice given 1.75% or 3.5% diethylene glycol consumed significantly more drinking water than did the controls. On the basis of water consumption and body weight data, the 0, 0.35, 1.75 and 3.5% dose groups were equivalent to average daily intakes of 0, 612, 3,062 or 6,125 mg/kg/day, respectively. There was no treatment-related mortality. In the 3.5% dose group, there was significant decreases in the number of litters produced per pair, number of live pups per litter, proportion of pups born alive, and the absolute and adjusted pup weights. A significant dose-related trend for reduced absolute pup weights was also observed. Exposure to the 3.55 dose group also resulted in a significant increase in the cumulative days to litter and fewer breeding pairs were able

to produce litters: 82%, 76%, and 59% of the pairs exposed to 3.5% in the diet produced the third, fourth or fifth litters, respectively, whereas 97-100% of the control group produced litters.

Crossover mating: The mating index and the fertility of the 3.5% dosed males or females were unaffected compared with the control mice. However, live pup weight was decreased in the highest-dose group, in which a 9% difference was observed for the offspring of the control males and the treated females. At the end of this test the parental animals (F0 of breeding study) were necropsied. For the male mice there were no significant differences in the body or organ weights, either absolute or adjusted for body weight. Analysis of the cauda epididymal contents of F0 males at necropsy indicated that there were no effects of diethylene glycol in the highest-doses group on the sperm concentration or the percentage of motile or abnormal sperm. The mean body weight of the 3.5% dosed F0 females was significantly decreased relative to the control females. The magnitude of this decrease was approximately 7%. These animals also exhibited significantly decreased absolute liver and pituitary weights, but their organ-to body weight ratios were not different from controls. There were no significant treatment-related gross or histopathological lesions in the organs examined from the male and female F0 mice (Williams et al., 1990) [Kl score = 2].

I. Developmental Toxicity

Time-pregnant CD rats were dosed by oral gavage with 0, 1,118, 4,472 or 8,944 mg/kg on gestational days 6-15. In the high-dose females, there were reduced body weight gain, reduced food consumption, increased water consumption, increased liver and kidney weights and histopathological changes in the kidney. The mid-dose females exhibited only increased water consumption. There were no treatment-related effects on corpora lutea or implantations. Foetal body weights were reduced in the high-dose animals. Total or individual external or visceral variations were similar between treated and control groups; however, individual skeletal variations were significantly increased in the mid- and high- dose groups. The pattern of delayed ossification was considered consistent with reduced foetal body weight. Malformations were similar between treated and control groups. The maternal and developmental NOELs for this study were considered to be 1,118 mg/kg/day (Ballantyne and Snellings, 2005) [Kl score = 2].

Time-pregnant CD-1 mice were dosed by oral gavage with 0, 559, 2,795 or 11,180 mg/kg/day during gestational days 6-15. In the high-dose females, there was mortality, clinical signs, and increased water consumption; only increased water consumption was observed in the mid-dose females. Foetal body weights were significantly reduced in the high-dose animals. There were no increases in variations or malformations between treated and control animals. The maternal and developmental NOELs were 559 and 2,795 mg/kg/day, respectively (Ballantyne and Snellings, 2005) [Kl score = 2].

Groups of 15 pregnant Himalayan rabbits were administered oral (gavage) doses of 0, 100, 400 or 1,000 mg/kg DEG on gestational days 7-19. No maternal toxicity was observed at any of the DEG doses administered. The foetal and litter incidence of skeletal, soft tissue and external anomalies or variations were comparable to those of the control and/or historical control groups. The authors set the maternal and developmental toxicity NOEL at greater than 1,000 mg/kg (Hellwig et al., 1995) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The lowest NOAEL reported in the repeat dose toxicity study is 105 mg/kg/day based on the 225-day rat dietary study. Although, there was a 13.2% increase in oxalate excretion at this dose level, this was considered a biomarker and not an indicator of toxicity. At 0.4% (the LOAEL), there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The NOAEL of 105 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x U_{FD})

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 105/(10 x 10 x 1 x 1 x 1) = 105/100 = 1.0 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (1.05 x 70 x 0.1)/2 = 3.7 mg/L

B. Cancer

A two-year study of in rats showed no carcinogenic effects when diethylene glycol was administered in drinking water (Hiasa et al., 1990). In older studies, bladder tumours were observed in rats given diethylene glycol in feed; the tumours are considered to be the result of physical irritation from the bladder stones that also were noted in the same animals (Fitzhugh and Nelson, 1946; Weil et al., 1965). It cannot be ruled out that these older studies, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on diethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Diethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	75,200	2	ECHA
Oncorhynchus mykiss	96-hour LC_{5}	66,000	2	ECHA
Daphnia magna	24-hour EC_{50}	>10,000	2	ECHA
Daphnia magna	48-hour EC_{50}	65,980	2	ECHA
Daphnia magna	48-hour EC_{50}	62,630	2	ECHA

Chronic Studies

In ECHA, the aquatic toxicity of the 'ethylene glycol and higher glycols' (mono-, di-, tri-, tetra- and pentaethylene glycol) is evaluated in a read-across approach. Data on all three trophic levels (fish, *daphnia*, algae) are available to describe the aquatic toxicity of the glycol read-across members. Due to the fact, that not for each single substance data for all required endpoints are available, a weight of evidence approach is used, which includes additional information based on QSAR calculation with the EpiWin-Program ECOSAR v1.11. Measured data, as well as estimated data, demonstrate that all glycols within the read-across are not harmful to aquatic organisms. No adverse effects on aquatic organisms occurred up to concentrations above 100 mg/L (ECHA).

No data for fish was available for diethylene glycol. However, chronic studies for fish are available for ethylene glycol (CAS No.: 107-21-1). The 7-day NOEC for the fathead minnow (*Pimephales promelas*) was determined to be 15,380 mg/L based on the weight of the test organisms (ECHA) [Kl Score = 2].

No data for invertebrates was available for diethylene glycol. However, three studies were conducted with Dapnids (*Ceriodaphnia dubia* or *Daphnia magna*) for ethylene glycol (CAS-No.: 107-21-1) or triethylene glycol (CAS No.: 112-27-6). The study with ethylene glycol was conducted according to USEPA guideline 600/4-89/001 with *Ceriodaphnia dubia* as test species. The 7-day NOEC for reproduction was determined to be 8,590 mg/L ethylene glycol (nominal). Two studies

measured the effect of triethylene glycol on the reproduction of *Daphnia magna*. One study was conducted according to the national standard ASTM (E 47.01, Draft No. 1, "Draft proposed standard practice for conducting renewal life cycle toxicity tests with Daphnia magna"). In this test the Daphnids were exposed to triethylene glycol for 21 days. Based on reproduction the reported NOEC is > 15,000 mg/L triethylene glycol (nominal) (ECHA) [KI Score = 2].

Data for algae was available for diethylene glycol. The 8-day TGK to algae *Scenedesmus quadricauda* was determined to be 2,700 mg/L for diethylene glycol (ECHA) [KI score = 2].

From the QSAR calculations it can be expected for diethylene glycol that algae are slightly more sensitive (ChV = 1,200 mg/L) than invertebrates (ChV = 1,891 mg/L) or fishes (ChV = 7,694 mg/L) (ECHA) [KI Score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for diethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C50 values are available for fish (66,000 mg/L), and Daphnia (> 10,000 mg/L). Results from a chronic algae study is available on diethylene glycol (2,700 mg/L). On the basis that the data consists of short-term results from two trophic levels and a long-term result from one trophic level, an assessment factor of 100 has been applied to the lowest reported value, which is the chronic value for algae. The $PNEC_{water}$ is 27 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 17.3 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.89/1280) \times 1000 \times 27$
$= 17.3$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.89\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.36 mg/kg soil dry weight.

The calculations are as follows:

$PNECsoil = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 27

= 0.36 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diethylene glycol has been shown to be readily biodegradable; thus, it does not meet the screening criteria for persistence.

The calculated log K_{ow} is -1.98, and the experimental BCF is 100. Thus, diethylene glycol does not meet the screening criteria for bioaccumulation.

The lowest chronic toxicity value for diethylene glycol is > 0.1 mg/L. Thus, diethylene glycol does not meet the criteria for toxicity.

Therefore, diethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELING (ABSTRACTED FROM PUBCHEM)

A. Classification

Irritant

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS) (ABSTRACTED FROM PUBCHEM)

A. First Aid

Eye Contact

First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.\

Skin Contact

IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Inhalation

IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

Ingestion

DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious,

do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport the victim to a hospital.

Notes to Physician (abstracted from PubChem)

The patient should be resuscitated with isotonic crystalloidal fluids, and acidosis should be corrected. Early treatment with a competitive ADH inhibitor (e.g., 4-methylpyrazole or ethanol), hemodialysis and supportive care offer the best hope for patient recovery.

Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand-valve resuscitator, bag-valve-mask device or pocket mask, as trained. Perform CPR as necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature.

Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary oedema and treat if necessary. Monitor for shock and treat if necessary. Anticipate seizures and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex and does not drool. Administer activated charcoal.

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary oedema or is in severe respiratory distress. Positive-pressure ventilation techniques with a bag-valve-mask device may be beneficial. Consider drug therapy for pulmonary oedema. Monitor cardiac rhythm and treat arrhythmias if necessary. Start IV administration of D5W /SRP: "To keep open", minimal flow rate. Use 0.9% saline (NS) lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload. Treat seizures with diazepam or lorazepam. Use proparacaine hydrochloride to assist eye irrigation.

Medical Conditions Aggravated by Exposure

Respiratory conditions (asthma, etc.)

Emergency Personnel Protection

Wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Use water spray to keep fire-exposed containers cool.

B. Fire Fighting Information (abstracted from Comet Chemical SDS 2013)

Extinguishing Media

Use powder, alcohol-resistant foam, water spray, carbon dioxide.

Specific Exposure Hazards

Combustible when exposed to heat or flame; can react with oxidising materials.

Special Protective Equipment for Firefighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

C. Accidental Release Measures

Personal Precautions

Restrict access to area until completion of clean-up. Ensure clean-up is conducted by trained personnel only. All persons dealing with clean-up should wear the appropriate protective equipment including self-contained breathing apparatus.

Environmental Precautions

Ventilate the area. Stop spill or leak at source if safely possible. Dike for water control. Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g., sand), then place absorbent material into a container for later disposal.

Steps to be Taken if Material is Released or Spilled

Absorb spill with inert material (e.g., vermiculite, sand or earth), then place in suitable container. Clean up spills immediately, observing precautions in the Protective Equipment section. Provide ventilation.

D. Storage and Handling

General Handling

Wear protective gloves/clothing and eye/face protection. Use with adequate ventilation. Do not ingest. Do not breathe mist or vapour. Avoid contact with eyes, skin and clothing. Wash with soap and water after handling. Keep away from extreme heat and flame. Keep away from acids and other incompatibles. Keep containers tightly closed when not in use.

Other Handling Precautions

Wash thoroughly after handling. Use with adequate ventilation. Avoid breathing vapours from heated material. Avoid contact with eyes, skin and clothing. Keep container tightly closed. Wash clothing before reuse. Avoid breathing spray or mist.

Storage

Store in a cool, dry, well-ventilated area. Store away from areas of excessive heat, open flames, sparks and other possible sources of ignition. Keep away from incompatibles. Storage area should be

clearly identified, clear of obstruction and accessible only to trained and authorised personnel. Inspect periodically for damage or leaks.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for diethylene glycol.

Engineering Controls

Good general ventilation should be used. Localised ventilation should be used where vapours, mist or aerosols may be generated.

Personal Protection Equipment

Respiratory Protection: Wear an approved respirator with dust/mist pre-filters if any exposure to dust or mist is possible.

Hand Protection: Wear appropriate chemical-resistant gloves.

Skin Protection: Wear protective clothing to minimise skin contact.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Ballantyne, B., and Snellings, W.M. (2005). Developmental toxicity study with diethylene glycol by gavage to CD rats and CD-1 mice. Food Chem. Toxicol. 43: 1637-1646.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fitzhugh, O.G., and Nelson, A. (1946). Comparison of the chronic toxicity of triethylene glycol with that of diethylene glycol. J. Ind. Hyg. Tox. 25: 40-43.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. An experimental method for the assessment of the behavior of organic chemicals in the ecosphere by means of simple laboratory tests with 14C labeled chemicals. Chemosphere 14: 1589-1616.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Sci. 4: 67-80.

Hellwig, J., Klimisch, H.J., and Jäckh, R. (1995). Investigation of the prenatal toxicity of orally administered diethylene glycol in rabbits. Fundam. Appl. Toxicol. 28: 27-33. (1995).

Hiasa, Y., Kitahori, Y., Morimoto, J., Konishi, W., and Ohshima, M. (1990). Absence of carcinogenic or promoting effects of diethylene glycol on renal tumourigenesis in rats. J. Toxicol. Pathol. 3: 97-104.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Laug, E., Calvery, H.O., Morris, H.J., and Woodward, G. (1939). The toxicology of some glycols and derivatives. J. Ind. Hyg. Toxicol. 21: 173-201.

Lenk, W., Löhr, D., and Sonnenbichler, J. (1989). Pharmacokinetics and biotransformation of diethylene glycol and ethylene glycol in the rat. Xenobiotica 19: 961-979.

OECD. (2007). SIDS Dossier on the HPV Chemical Diethylene Glycol (CAS No. 111-46-6).

Pubchem. https://pubchem.ncbi.nlm.nih.gov/compound/DI_Hydroxyethyl_ether#section=InChI Accessed January 2022.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Verschueren, K. (1983). Handbook of Environmental Data on Organic Chemicals, 2nd Edition, Van Nostrand, New York: 1,310

Wegener, H. (1953). The reproductive capacity of rats after the action of diethylene glycol. Arch. Exper. Path. u. Pharmakol. 220: 414-417.

Weil, C.S., Carpenter, C. and Smyth, H.F. (1965). Urinary bladder response to diethylene glycol. Arch. Environ. Health 77: 569-581.

Williams, J., Reel, J., George, J., and Lamb, IV, J. (1990). Reproductive effects of diethylene glycol and diethylene glycol monoethyl ether in Swiss CD-1 mice assessed by a continuous breeding protocol. Fundam. App. Toxicol. 74: 622-635.

DISODIUM OCTABORATE TETRAHYDRATE

This dossier presents the most critical studies pertinent to the risk assessment of disodium octaborate tetrahydrate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC) [Disodium octaborate]: disodium;(9,11-dioxido-5-oxoboranyloxy-2,4,6,8,10,12,13-heptaoxa-1,3,5,7,9,11-hexaborabicyclo[5.5.1]tridecan-3-yl)oxy-oxovorane

CAS RN: 12280-03-4

Molecular formula: $Na_2B_8O_{13}\bullet 4H_2O$

Molecular weight: 412.4

Synonyms: Disodium octaborate tetrahydrate; disodium octaborate

SMILES (disodium octaborate): B(=O)OB1OB2OB(OB(OB(O2)OB(O1)OB=O)[O-])[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Disodium Octaborate Tetrahydrate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odorless, crystalline powder	1	ECHA
Melting Point	>1,000°C	1	ECHA
Density	1.874 g/cm^3	1	ECHA
Vapor Pressure	9.9 x 10^{-17} Pa @ 25°C	1	ECHA
Water Solubility	223.65 g/L @ 20°C	1	ECHA
Auto flammability	Not a self-heating substance	1	ECHA

Exposure to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. The B equivalents used are a generic designation rather than a designation of the element boron. The factor for converting disodium octaborate tetrahydrate to B-equivalents is 0.2096.

III. ENVIRONMENTAL FATE PROPERTIES

Many minerals contain boron, which is present as the sodium or calcium borate salt. Thus, boron is ubiquitous and widely distributed in the environment. It is present in rocks, soil and water and is released into the environment primarily from the weathering of rock and soil, volatilization of sea water, and anthropogenic activity.

Disodium octaborate tetrahydrate ($Na_2B_8O_{13}\bullet 4H_2O$) is very soluble in water, with the main species in freshwater being the borate ion $[B(OH)_4]^-$ and boric acid $B(OH)_3$, depending on the pH. The relative proportion of boric acid and borate ions is controlled by pH: $B(OH)_3 + 2H_2O \Leftrightarrow [B(OH)_4]^- + H_3O^-$. In dilute aqueous solutions, boric acid does not dissociate at pH <7; at pH values between 7 and 11, both boric acid and borate ions are present. In dilute aqueous solutions and physiological conditions, the predominant species present is un-dissociated boric acid. So, the consideration of boric acid addresses the relevant environmental stability properties for borates.

In natural waters, boron forms stable species and exists primarily as un-dissociated boric acid $[B(OH)_3]$ and complex polyanions (*e.g.,* $[B(OH)_4]^-$). These forms of boron are highly soluble and not easily removed from solution by natural mechanisms. Borate and boric acid are in equilibrium depending on the pH of the water. At an acidic pH, boron exists in solution mainly as un-dissociated boric acid, whereas at alkaline pH it is present as borate ions.

Degradation is not applicable to inorganic borates, such as disodium octaborate tetrahydrate. It is not subject to hydrolysis, photodegradation, or biodegradation (ECHA). Inorganic borates are subject to chemical transformation processes (adsorption, complexation, precipitation, fixation) once released into the environment (ECHA).

The WHO review of boron (WHO, 1998) noted that “highly water soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as un-dissociated and highly soluble boric acid at neutral pH”. A BCF of <0.1 was reported in Chinook salmon fed boron-supplemented diets for 60 to 90 days (Hamilton and Wiedmeyer, 1990).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Disodium octaborate tetrahydrate exhibits low acute toxicity by the oral and dermal routes. It is not a skin or eye irritant, or a skin sensitizer. Toxicity studies on boric acid, borax (disodium tetraborate decahydrate), and boron oxide have been used to read-across to disodium octaborate tetrahydrate. This is justified because, in aqueous media at physiological pH, all of these inorganic borate compounds will predominantly exist as un-dissociated boric acid. The developing fetus and the testes are the two most sensitive targets of boron toxicity in multiple species. The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic epithelium, impaired spermatogenesis, reduced fertility, and sterility. The developmental effects from boron exposure include high prenatal mortality; reduced fetal body weight; and malformations and variations. Repeated inhalation exposure to boron oxide resulted in slight irritation to the respiratory tract, but no systemic toxicity. Boric acid was not genotoxic; and boric acid and borax was not carcinogenic to rodents.

B. Acute Toxicity

The oral LD_{50} of disodium octaborate tetrahydrate in rats is 2,550 mg/kg (ECHA) [Kl. score = 1]. The oral LD_{50} of boric acid in rats is 3,450 mg/kg (ECHA) [Kl. score = 1]. The oral LD_{50} of anhydrous boric acid in rats is >2,500 mg/kg. [Kl. score = 1].

There are no acute inhalation studies on disodium octaborate tetrahydrate. The 4-hour inhalation LC_{50} value for boric acid in rats is >2.01 mg/L. The mass median aerodynamic diameter (MMAD) was 2.8 µm (ECHA) [Kl. score = 1]. In another study, the 4-hour inhalation LC_{50} value for boric acid in rats was >2.03 mg/L (ECHA) [Kl. score = 1]. The 4-hour inhalation LC_{50} value for disodium tetraborate pentahydrate in rats is >2.04 mg/L (ECHA) [Kl. score = 1].

The dermal LD_{50} of disodium octaborate tetrahydrate in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 1]. The dermal LD_{50} of boric acid in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 1]. The dermal LD_{50} of sodium tetraborate pentahydrate in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 1].

C. Irritation

Application of 0.5 g. of disodium octaborate tetrahydrate to the skin of rabbits for 4 hours under occlusive conditions was not irritating. The mean of the 24, 48, and 72 hour scores were: 0.22 for erythema and 0.00 for edema (ECHA) [Kl. scores = 1].

Application of 0.5 g. of boric acid to the skin of rabbits for 24 hours under occlusive conditions was not irritating. The mean of the 24 and 72 hour scores were: 0.13 for erythema and 0.00 for edema (ECHA) [Kl. scores = 1]. Application of 0.5 g. of sodium tetraborate pentahydrate to the skin of rabbits for 4 hours under occlusive conditions

was not irritating. The mean erythema and edema scores were 0.00 (ECHA) [Kl. scores = 2].

Disodium octaborate tetrahydrate was not considered to be an eye irritant when 0.053 or 0.049 g. was instilled into the eyes of rabbits (ECHA) [Kl. scores = 1]. Instillation of 0.08 mL boric acid into the eyes of rabbits was slightly irritating. The mean of 24, 48, and 72 hours scores were: 0.22 for corneal opacity; 0.22 for iridial lesions; 2.8 for conjunctival redness; and 1.89 for chemosis (ECHA) [Kl. score = 1].

D. Sensitization

Disodium octaborate tetrahydrate was not a skin sensitizer to guinea pigs in a Buehler test (ECHA) [Kl. score = 1].

Boric acid was not a skin sensitizer to guinea pigs in a Buehler test (ECHA) [Kl. score = 1]. Sodium tetraborate pentahydrate was not a skin sensitizer to guinea pigs in a Buehler test (ECHA) [Kl. score = 1]. Sodium tetraborate decahydrate was not a skin sensitizer to guinea pigs in a Buehler test (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

<u>Oral</u>
Male and female SD rats were given in their feed boric acid at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg-day, respectively (EPA, 2004). By week 6, all of the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws, and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen ovary, and adrenal weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes, and adrenal weights. The adrenals of 4 of the 1,750 ppm males showed minor increases in lipid content and size of the cells in the zona reticularis. Atropied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. One 525 ppm male had partial testicular atrophy. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female SD rats were given in their diet borax at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg-day, respectively (EPA, 2004). By week 6, all of the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws, and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen and ovary weights; the 1,750 ppm

males showed reduced liver, spleen, kidney, testes, and brain weights. The adrenals of the majority of the 1,750 ppm males and females showed slight to moderate increases in lipid content and size of the cells in the zona reticularis. Atropied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. Four 525 ppm males had partial testicular atrophy. Spermatogenic arrest was found in one 525 ppm male. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female B6CF1_1 mice were given in the diet 0, 1,200, 2,500, 5,000, 10,000 or 20,000 ppm boric acid for 13 weeks (control and highest dose group) or 16 weeks (remaining dose groups). These dietary levels correspond to approximately 0, 34, 70, 141, 281 and 563 mg B/kg-day for males, respectively; and 0, 47, 97, 194, 388 and 776 mg B/kg-day for females, respectively (EPA, 2004). There was mortality (8/10 males; 6/10, females) in the 20,000 ppm, as well as hyperkeratosis and acanthosis. One male also died in 10,000 ppm group. Degeneration or atrophy of the seminiferous tubules occurred in the $\geq$5,000 ppm males. Minimal to mild extramedullary hematopoiesis of the spleen was observed in all dose groups. The LOAEL for this study is 1,200 ppm, corresponding to 34 and 47 mg B/kg-day for males and females, respectively (NTP 1987). [Kl. score = 2]

Male and female SD rats were given in their diet 0, 117, 350 or 1,170 ppm boric acid for two years. The average intake has been estimated to be approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively (EPA, 2004). The 1,170 ppm rats had decreased food consumption during the first 13 weeks of the study and suppressed growth throughout the study. Signs of toxicity in the 1,170 ppm animals included swelling and desquamation of the paws, scaly tails, inflammation of the eyelids, and bloody discharge from the eyes. All of the 1,170 ppm males had testicular atrophy at the 6, 12 and 24 month time points. The seminiferous epithelium was atrophied, and the tubular size in the testes was decreased. There were significant decreases in the absolute and relative testes weights. Brain and relative thyroid weights were increased. The NOAEL for this study is 350 ppm B equivalents or 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female B6C3F$_1$ mice were given 0, 2,500 or 5,000 ppm boric acid in their feed for 103 weeks (NTP, 1987). These dose levels were equivalent to 0, 275 or 550 mg/kg-day boric acid or 0, 48 or 96 mg B/kg-day (EPA, 2004). There was reduced survival in the male mice, which was significantly different from the controls in the 2,500 ppm mice after week 63 and in the 5,000 ppm mice after week 84. The survival rates by the end of the study were 82, 60 and 44% in the 0, 2,500, and 5,000 ppm males, respectively; and 66, 66 and 74% in the 0, 2,500, and 5,000 ppm females, respectively. Mean body weights were 10-17% lower in the 5,000 ppm animals after 32 (males) or 52 (females) weeks compared to the controls There was testicular atrophy and interstitial cell hyperplasia in the testes of the 5,000 ppm males. A dose-related increase in the

incidences of splenic lymphoid depletion in male mice was also observed. NTP considered this lesion to be associated with stress and debilitation, and it is reflected in the increased mortality in these groups of male mice. The NOAEL for this study is (NTP, 1987). [Kl. score = 2]

Inhalation

Male and female rats were exposed by inhalation to 0, 77, 175, or 470 mg/m^3 boron oxide. The exposures were 6 hours/day, 5 days/week for 24, 12, and 10 weeks for the 77, 175, and 470 mg/m^3 concentrations groups, respectively. The MMAD were 2.5, 1.9, and 2.4 µm for the 77, 175, and 479 mg/m^3 concentrations groups, respectively. There was no evidence of systemic toxicity. Some of the 470 mg/m^3 had reddish exudate from the nose. As these animals were covered with dust, this effect may have been local irritation of the nose and from the animals scratching the nose. The NOAEL for systemic toxicity is 470 mg/m^3, the highest exposure concentration tested. The NOAEL for localized effects (irritation) is 175 mg/m^3 (ECHA). [Kl. score = 2]

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

There are no *in vitro* genotoxicity studies on disodium octaborate tetrahydrate. Table 2 presents the results of the *in vitro* genotoxicity studies on boric acid.

Table 2: *In vitro* Genotoxicity Studies on Boric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations	-	-	1	ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
(Chinese Hamster Ovary cells)				
Chromosomal aberrations (Human peripheral lymphocytes)	NS	+	2	ECHA
Unscheduled DNA synthesis (rat liver cells)	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable; NS, not specified.

In Vivo Studies

No studies are available on disodium octaborate tetrahydrate.

Male and female Swiss Webster mice were given two daily doses of 0, 225, 450, 900, 1,800, or 3,500 mg/kg boric acid. The frequency of micronucleated polychromatic erythrocytes were not increased at any dose level (ECHA) [Kl. score = 1].

G. Carcinogenicity

Oral
No studies have been conducted on disodium octaborate tetrahydrate.

Male and female SD rats were given in their diet disodium tetraborate decahydrate (Borax) or boric acid at doses of 0, 117, 350, or 1,170 ppm as B equivalents (approximately 0, 5.9, 17.5, or 58.5 mg B/kg-day) for two years. There was no mention of tumors in the report. Nevertheless, NTP (1987) concluded that this study provided adequate data on the lack of carcinogenic effects of boric acid in rats (Weir and Fisher, 1972; EPA, 2004).

Male and female B6C3F_1 mice were given in their diet 0, 2,500, or 5,000 ppm boric acid for 103 weeks. The dietary levels are equivalent to 0, 446, or 1,150 mg/kg-day boric acid or 0, 78.1, or 201.3 mg B/kg-day. There was no evidence of carcinogenicity (NTP, 1987). [Kl. score = 2]

H. Reproductive Toxicity

A three-generation reproductive toxicity study was conducted in albino rats (strain not specified) with boric acid. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively). In

the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170 ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

A three-generation reproductive toxicity study was conducted in albino rats (strain not specified) with disodium tetraborate decahydrate. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170 ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

In a continuous breeding protocol, male and female CD-1 mice were given in their diet 0, 1,000, 4,500 or 9,000 ppm boric acid in their feed. The authors estimated that the average daily intakes were: 0, 26.6, 111, and 220 mg B/kg-day to males; and 0, 31.8, 152, 257 mg B/kg-day to females. Boric acid consumption did not differ among the groups. There were no litters in the 9,000 ppm breeding pairs. At 4,500 ppm, there was a successful first litter, after which there was a progressive decrease in fertility; only one pair produced a fourth and fifth litter. All fertility indices were affected in the 4,500 ppm group. A complete crossover mating trial was conducted using control mice and the 4,500 ppm mice. The results showed that the probable cause of the reduced fertility was a decrement in male fertility. A dose-related decrease in body, testicular and epididymal weights was observed in the 4,500 and 9,000 ppm F_0 males. Sperm count was significantly decreased in these two dose groups, and percent motile sperm was decreased in all dose groups. Testicular histopathology showed seminiferous tubular atrophy in the 9,000 ppm males and partial atrophy of the seminiferous tubules in the 4,500 ppm males. There were no histopathologic changes in the 4,500 ppm females. No statistically significant decreases in mating index, fertility index, or live pups/litter in the 4,500 ppm females, but the number of days to litter in this dose group was increased. Estrous cyclicity was unaffected. Reproductive organ weights were unaffected, but relative maternal liver and kidney/adrenal weights were reduced. An F_1 fertility trial was performed using offspring from the 1,000 ppm groups. There was no decreases in mating, fertility or reproductive performance. The F_2 adjusted live pup weight was slightly, but significantly, reduced from controls. A clear NOAEL for

reproductive toxicity in males was not seen in this study. The 1,000 ppm males had decreased sperm motility in the F_0 generation and decreased sperm concentration in the F_1 generation. Decreased F_2 pup relative body weight was statistically significant from controls. The NOAEL in this study for females is 1,000 ppm boric acid or 32 mg B/kg-day). The LOAEL in this study for males is 1,000 ppm or 27 mg B/kg-day; a NOAEL was not established (Fail *et al.* 1991). [Kl. score = 2]

I. Developmental Toxicity

Pregnant female SD rats were given 0, 0.1, 0.2 or 0.4% boric acid in their feed on gestational days (GD) 0 to 20 or 0.8% boric acid on GD 6 to 15. The average amounts of boric acid ingested were estimated to be 0, 78, 163, 330 or 539 mg/kg-day (0, 13.6, 28.5 or 57.7 mg B/kg-day), respectively. Effects on the pregnant rats were altered food and/or water intake at $\geq$0.2% boric acid, increased liver and kidney weights relative to body weights at $\geq$0.2%, reduced weight gain at $\geq$0.4%, and increased corrected weight gain at 0.4% boric acid. There was a reduction in fetal body weights in all treated groups (94, 87, 63, and 47% of control weight, respectively). Increased malformations occurred at $\geq$0.2%, and prenatal mortality was increased at 0.8%. There was a dose-response for altered skeletal morphology in rats ($\geq$0.1%), and specific findings were significantly elevated above controls at $\geq$0.2%. Specifically, there was an increased incidence of short rib XIII (a malformation) and a decreased incidence or rudimentary or full rib(s) at lumbar I (an anatomical variation) (Heindel *et al.* 1992). [Kl. score = 2]

Pregnant female SD rats were given in their feed 0, 0.025, 0.005, 0.075, 0.1 or 0.2% boric acid on GD 0 to 20. Approximately half of the dams were terminated on GD 20, and the remaining dams delivered their litters. Pup growth and viability were monitored until postnatal day (PND) 21. The average amounts of boron ingested on GD 20 were: 0, 3.3, 6.3, 9.6, 13.3, and 25 mg B/kg-day], respectively. The average amounts of boron ingested on PND 21 were : 0, 3.2, 6.5, 9.7, 12.9, and 25.3 mg B/kg-day, respectively. There were no maternal deaths and no treatment-related clinical signs. Maternal body weights were similar across all groups during gestation. However, decreased maternal body weights (GD 19 and 20 at sacrifice) and decreased maternal body weight gain (GD 15-18 and GD 0-20) were statistically significant in trend tests. There was a 10% reduction in gravid uterine weight (statistically significant) in the 0.2% group. Corrected maternal weight (maternal gestational weight minus reduced gravid uterine weight) was unaffected by treatment. Feed intake in the 1,000 ppm dams was minimally affected and only during the first three days of dosing. Water consumption was higher in the treated groups after GD 15. The number of corpora lutea and uterine implantation sites, and the percentage of preimplantation loss were similar across all groups. Increased relative kidney weights were increased in the 0.2% group. There were no differences in the viability of the offspring between treated and controls. On GD 20, fetal body weight was 94% and 88% of controls in the 0.1% and 0.2% groups, respectively; recovery was complete at birth (~GD 22). The incidence of short rib XIII was increased on GD 20 in the $\geq$0.1% groups, but only in the 0.2% group at PND 21. The

incidence of wavy rib was increased on GD 20 in the ≥0.1% group; the reversibility of this effect was confirmed on PND 21. There was a slight decrease in extra lumbar ribs in the 0.2% group on GD 20, and extra lumbar ribs were seen in the 0.2% group on PND 21. The developmental NOAEL was considered to be 0.075% boric acid or 9.6 mg B/kg-day on GD 20; and 0.1% boric acid or 12.9 mg B/kg-day on PND 21 (Price *et al.* 1996a). [Kl. score = 1]

Pregnant Swiss mice were given in their diet 0, 0.1, 0.2 or 0.4% boric acid on gestational days (GD) 0 to 17. The average amounts of boric acid ingested were estimated to be 248, 452 or 1,003 mg/kg-day (0, 43.4, 79.0 or 175.3 mg/B/kg-day), respectively. Maternal toxicity consisted of mild kidney lesions (≥0.1%), increased water intake and relative kidney weights (0.4%), and decreased water intake during treatment. Fetal body weights were reduced in the ≥0.2% groups, and there were increased incidences of resorptions and malformed fetuses per litter in the 0.4% group. The LOAEL for maternal toxicity is 248 mg/kg-day boric acid or 43.4 mg B/kg-day; a NOAEL was not established. The NOAEL for developmental toxicity is 248 mg/kg-day boric acid or 43.4 mg B/kg-day (Heindel *et al.* 1992). [Kl. score = 2]

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 62.5, 125 or 250 mg/kg boric acid (0, 10.9, 21.9 or 43.7 mg B/kg) during GD 6-19. Feed intake was in the 250 mg/kg maternal animals during the exposure period, but it was increased in the ≥125 mg/kg dose groups. In the 250 mg/kg group, maternal body weights during GD 9-30, weight gain during GD 6-19, gravid uterine weight, and number of corpora lutea per dam were significantly reduced. In the ≥125 mg/kg groups, maternal corrected gestational weight gain was increased compared to controls. Maternal liver weights were unaffected by treatment. In the 250 mg/kg group, relative, but not absolute, kidney weights were increased, although no effects in the kidney were noted in the histopathological examination. Prenatal mortality was increased in the 250 mg/kg group (90% resorptions/litter versus 6% for controls); the proportion of pregnant females with no live fetuses was increased (73% versus 0%), and live litter size was reduced (2.3 fetuses versus 8.8). Thus, there were only 14 live fetuses (6 live litters) available for evaluation in the 250 mg/kg group. The percentage malformed fetuses/litter was increased in the 250 mg/kg group, primarily due to cardiovascular defects (72% versus 3% of controls). There was no definitive maternal or developmental toxicity in the 62.5 or 125 mg/kg dose groups. The NOAEL for maternal and developmental toxicity is 125 mg/kg-day boric acid or 21.9 mg B/kg-day (Price *et al.* 1996b). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for disodium octaborate tetrahydrate follow the methodology discussed in enHealth (2012). The approach used to develop

drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The developing fetus and the testes are the two most sensitive targets of boron toxicity in multiple species (EPA, 2004; ECHA, 2010). The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic epithelium, impaired spermatogenesis, reduced fertility, and sterility (EPA, 2004). The developmental effects from boron exposure include high prenatal mortality; reduced fetal body weight; and malformations and variations (EPA, 2004).

The U.S. Environmental Protection Agency (U.S. EPA) derived an Oral Reference Dose (RfD) for boron of 0.2 mg B/kg-day (U.S. EPA 2004) based on developmental effects in rats from two studies (Price *et al.* 1996a; Heindel *et al.* 1992).

The RfD was derived using the benchmark dose (BMD) method ($BMDL_{05}$ from Allen *et al.* 1996) using a data derived uncertainty factor of 66. Decreased fetal body weight ($BMDL_{50}$ = 59 mg boric acid/kg-day or 10.3 mg B/kg-day) was considered by Allen *et al.* (1996) as the most suitable endpoint for developing a point of departure, because the benchmark doses calculated for the other endpoints (incidence of total malformations, enlarged lateral ventricles in the brain, shortening of rib XIII, and variations of the first lumbar rib) were higher.

Derivation of an Oral Reference Dose

Oral RfD = $BMDL_{05}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10.42 [3.16, toxicodynamics; 3.3, toxicokinetics]
UF_H (intraspecies variability) =6.32 [3.16, toxicodynamics; 2.0, toxicokinetics]
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 10.3/(7.9 x 6.3 x 1 x 1 x 1) = 10.3/66 = 0.2 mg B/kg-day

Derivation of a drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.2 x 70 x 0.1)/2 = 0.7 mg/L

Australian drinking water guideline

The Australian drinking water guideline for boron is 4 mg/L (ADWG, 2011).

B. Cancer

There was no evidence of carcinogenicity in rat and mouse chronic studies conducted on disodium tetraborate decahydrate and/or boric acid. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Disodium octaborate tetrahydrate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Aquatic Toxicity

The summary of the data used by ANZECC to develop a water quality guideline for boron is as follows:

Freshwater Fish
The chronic values for four species ranged from 40 µg/L (32-day LOEC in *O. mykiss*) to 27,600 µg/L (32-day LOEC in *O. mykiss*). Other *O. mykiss* data were order of magnitude higher than 40 µg/L, including those from the same paper (2,100 µg/L for a 87-day NOEC and 27,600 µg/L for a 32-day LC_{50}). All other geometric means were >4,000 µg/L.

Freshwater Crustaceans

The chronic data ranged from a 21-day MATC value of 4,665 µg/L for *Daphnia magna* based on growth to an LC_{50} value of 54,200 µg/L from a 21-day *Daphnia* study. A measured NOEC of 6,000 µg/L based on reproduction was also reported.

Freshwater Algae

The data ranged from a 14-day NOEC of 400 µg/L for *Chlorella pyrenoidosa* to a NOEC of 5,200 µg/L for *Chlorella vulgaris*. Both values are based on population growth.

C. Terrestrial Toxicity

There are considerable number of terrestrial toxicity studies on borates. See the ECHA REACH database (ECHA) for summaries of the relevant studies.

Avian Toxicity Studies

The avian toxicity studies conducted on disodium octaborate and boric acid are presented in Table 3.

Table 3: Avian Toxicity Studies on Disodium Octaborate and Boric Acid

Test Species	Test Substance	Endpoint	Results	Klimisch score	Reference
Mallard duck	Disodium octaborate	dietary LC_{50}	>2,100 mg B/kg food	1	EU, 2007
Bobwhite quail	Boric acid	dietary LC_{50}	>983 mg B/kg food	1	EU, 2007
Bobwhite quail	Disodium octaborate	Oral gavage LD_{50}	>527 mg B/kg bw	4	EU, 2007
Bobwhite quail	Disodium octaborate	dietary LC_{50}	>2,100 mg B/kg food	1	EU, 2007

The following information was also found in an EPA Reregistation Elibility Decision (RED) document for Boric Acid and its Sodium Salts (EPA, 1993): the LD_{50} for bobwhite quail is >2,510 mg/kg. The dietary LC_{50} for mallard duck and bobwhite quail are >5,620 ppm and 10,000 ppm, respectively

D. Calculation of PNEC

PNEC water

The ANZECC water quality guideline (2000) used a "freshwater high reliability trigger value for boron of 370 µg/L was calculated using the statistical distribution method at 95% protection."

"Although the 95% protection level is higher than the 32-day LOEC of 100 µg/L for O. mykiss, this figure appeared anomalous and other data on this species showed much less toxicity. The low figure may need to be checked. The 95% figure is considered sufficiently protective for slightly-moderate disturbed ecosystems" (ANZECC, 2000).

PNEC sediment

No experimental toxicity data on sediment organisms are available. Disodium octaborate tetrahydrate dissociates completely in water and its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as disodium octaborate tetrahydrate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on the its properties, no adsorption of disodium octaborate tetrahydrate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC Soil

In the ECHA REACH database (ECHA), a $PNEC_{soil}$ was derived for boron using the species sensitivity distribution method and an assessment factor of 2. The $PNEC_{soil}$ was determined to be 5.7 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Disodium octaborate tetrahydrate is an inorganic compound that dissociates completely to boric acid and the borate anion in aqueous media. Biodegradation is not applicable to these inorganic compounds; both boric acid and borate are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to disodium octaborate tetrahydrate.

Disodium octaborate tetrahydrate is a water-soluble substance that is not expected to bioaccumulate. Limited data indicate that bioaccumulation (BCF values are low) is not significant in aquatic and terrestrial food chains. Thus, it does not meet the criteria for bioaccumulation.

Boric acid and inorganic borates are reproductive toxicants and have been classified under GHS as known or presumed human reproductive toxicants (Category 1B). Thus, disodium octaborate tetrahydrate meets the PBT criteria of toxicity.

The overall conclusion is that disodium octaborate tetrahydrate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Reproductive Toxicant Category 1B

B. Labelling

Danger
According to the harmonised classification and labelling (ATP09) approved by the European Union, this substance may damage fertility and may damage the unborn child.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Swallowing small quantities (one teaspoon) will not cause any harm to adults. If larger amounts are swallowed, give two glasses of water to drink and seek medical attention. Never give anything by mouth to an unconscious person.

Notes to Physician

Observation only is required for adult ingestion of <5 grams. For ingestion of >5 grams, maintain adequate kidney function and force fluids.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Disodium octaborate tetrahydrate is a flame retardant. It is not flammable, combustible, or explosive.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eye, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage And Handling

General Handling
No special measures necessary provided product is used correctly.

Other Handling Precautions
Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for disodium octaborate tetrahydrate.

[The workplace exposure standard for disodium tetraborate decahydrate (borax) in Australia is 5 mg/m^3 as an 8-hour TWA. The workplace exposure standard for disodium tetraborate pentahydrate in Australia is 1 mg/m^3 as an 8-hour TWA.]

Engineering Controls
Ensure adequate ventilation. Localized ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment
Respiratory Protection:
Use respiratory protection when airborne concentrations are expected to exceed exposure limits.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Disodium octaborate tetrahydrate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Allen, B.C., Strong, P.L., Price, C.J., Hubbard, S.A., and Daston, G.P. (1996). Benchmark dose analysis of developmental toxicity in rats exposed to boric acid. Fundam. Appl. Toxicol. 32: 194-204.

ANZECC (2000). Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Volume 2, Aquatic Ecosystems – Rationale and Background Information, Australian and New Zealand Environment and Conservation Council (ANZECC) and Agriculture and Resource Management Council of Australia and New Zealand.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

ECHA (2010). Member state committee draft support document for identification of boric acid as a substance of very high concern because of its CMR properties. Available at: https://echa.europa.eu/documents/10162/d51fd473-40ec-4831-bc2d-6f53bdf9cbbe.

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

European Union [EU] (2007). European Union Risk Assessment Report on Disodium Tetraborate, Anhydrous Boric Acid, and Boric Acid, Crude Natural – Draft. Available at: https://echa.europa.eu/documents/10162/ea3533df-1457-4664-98d6-51b2f904af36

Fail, P.A., George, J.D., Seely, J.C., Grizzle, T.B., and Heindel, J.J. (1991). Reproductive toxicity of boric acid in Swiss (CD-1) mice: assessment using the continuous breeding protocol. Fundam. Appl. Toxicol. 17: 225-239.

Hamilton, S.J., and Wiedmeyer, R.H. (1990). Concentrations of boron, molybdenum and selenium in chinook salmon. Trans. Amer. Fisheries Soc. 119: 500-510.

Heindel, J.J., Price, C.J., Field, E.A., Marr, M.C., Myers, C.B., Morrissey, R.E., and Schwetz, B.A. (1992). Developmental toxicity of boric acid in mice and rats. Fundam. Appl. Toxicol. 18: 266-272.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

National Toxicology Program [NTP] (1987). Toxicology and Carcinogenesis Studies of Boric Acid (CAS No. 10043-35-3) in B6C3F_1 Mice. NTP TR 324, NIH Publication No. 88-2580. National Toxicology Program, U.S. Department of Health and Human Services, National Institute of Health.

Price, C.J., Strong, P.L., Marr, M.C., Myers, C.B., and Murray, F.J. (1996a). Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. Fundam. Appl. Toxicol. 32: 179-193.

Price, C.J., Marr, M.C., Myers, C.B., Seely, J.C., Heindel, J.J., and Schwetz, B.A. (1996b). The developmental toxicity of boric acid in rabbits. Fundam. Appl. Toxicol. 34: 176-187.

U.S. EPA (1993). Registration Elibility Decision (RED): Boric Acid and its Sodium Salts, EPA 738-R-93-017. Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency, September 1993.

U.S. EPA (2004). U.S. EPA (United States Environmental Protection Agency). Integrated Risk Information System (IRIS) – Boron and Compounds; CASRN 7440-42-8. Available at: http://www.epa.gov/iris.

Weir, R.J., Jr., and Fisher, R.S. (1972). Toxicologic studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

WHO (1998). Environmental Health Criteria 204, Boron, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland.

ETHANOL

This dossier on ethanol presents the most critical studies pertinent to the risk assessment of ethanol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Ethanol consumption in alcoholic beverages is out of the scope of this dossier. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ethanol

CAS RN: 64-17-5

Molecular formula: C_2H_6O

Molecular weight: 46.069

Synonyms: Ethyl alcohol, grain alcohol, alcohol, methylcarbinol, ethyl hydroxide, ethyl hydrate, algrain, alkohol, anhydrol

SMILES: CCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Ethanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless liquid with a mild odor.	2	ECHA
Melting point	-114°C	2	ECHA
Boiling point	78.2°C	2	ECHA
Density	0.789 g/cm^3 @ 20°C	2	ECHA
Vapor pressure	57.26 hPA @ 19.6°C	2	ECHA
Partition coefficient (log K_{ow})	-0.35 @ 24°C	2	ECHA
Water solubility	789 g/L @ 20°C	2	ECHA

Property	Value	Klimisch score	Reference
Flash point	13°C	2	ECHA
Auto flammability	>363 and <425°C	2	ECHA
Viscosity	1.17 mPa s @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Ethanol is readily biodegradable and not expected to bioaccumulate.

B. Biodegradation

Ethanol is readily biodegradable. The degradation of ethanol was approximately 74% and 84% (O_2 consumption) within 10 and 20 days, respectively, in a biodegradation test using a non-adapted domestic inoculum in a freshwater medium (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for ethanol. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} of -0.35 is 2.199 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.045 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on ethanol. Ethanol is not expected to bioaccumulate based on a log K_{ow} of -0.35 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

Human health toxicological information was obtained from Inventory Multi-Tiered Assessment and Prioritisation (IMAP), which is an assessment framework conducted via Australia's National Industrial Chemicals Notification and Assessment Scheme (NICNAS), unless otherwise cited. Statements regarding toxicity are based solely on the determination of applicable regulatory agency.

A. Summary

Ethanol has a low acute toxicity by the oral, dermal, and inhalation routes of exposure, as measured by lethality. Sublethal doses, however, have been shown to produce central nervous system depression, respiratory depression, and coma. Deaths were reported in rodent studies due to cardiorespiratory failure. Ethanol is not irritating to the skin, but it is slightly irritating to the eyes. Repeated exposures by the oral route have not resulted in any systemic toxicity to rodents, except from exposure to high doses. Evidence of the carcinogenicity of ethanol is confined to epidemiological studies assessing the impact of alcoholic beverage consumption. These do not indicate any such hazard exists from potential exposure to ethanol in the workplace or from the use of ethanol in consumer products (OECD, 2004). Ethanol is not genotoxic or mutagenic. Ethanol does not show specific reproductive or developmental toxicity. Any reproductive and developmental effects were only observed secondary to maternal toxicity.

B. Acute Toxicity

Oral

The chemical has low acute toxicity by oral exposure in animal tests. The median lethal dose (LD50) in rats is >2000 mg/kg bw. Observed sub-lethal effects included central nervous system depression, e.g. inebriation, disturbances of gait, dose-related decreases in responses to painful stimuli, respiratory depression, and coma. Deaths were reported due to cardiorespiratory failure (OECD, 2005; HSDB; REACH).

Dermal

Few studies are available on the dermal toxicity of the chemical. A poorly documented rabbit study reported death in one of four animals following a dose of 20000 mg/kg bw. Although limited data are available, the apparent low dermal toxicity from this study is regarded as consistent with low uptake of ethanol through intact skin. The median lethal dose (LD50) in rats is greater than 2000 mg/kg bw. Observed sub-lethal effects were not reported for the study (OECD, 2005; REACH).

Inhalation

The chemical has low acute toxicity by inhalation exposure in animal tests. The lowest reported median lethal concentration (LC50) is 124.7 mg/L/four hours in rats. Observed sub-lethal effects included attempts to escape, reddish-watery eyes, nasal secretions, closing of eyelids, snout wiping, intermittent respiration, loss of pain reflex, abdominal position, and apathy (OECD, 2005; REACH).

C. Irritation

The chemical is not regarded as irritating to skin. The chemical is frequently applied to skin as a biocidal surgical wipe (70–80 % concentration) and as a component of

cosmetics, personal care, and household cleaning products. There appear to be few documented concerns regarding skin irritation arising from these uses. Direct contact of the eye with the liquid chemical causes immediate discomfort accompanied by reflexive closure of the eye. Even though the acute effect subsides rapidly and the recovery is complete, foreign body type discomfort may persist for a day or two. Although inhaling the chemical at 5000 ppm (9600 mg/m^3) has been reported as irritating in humans; lacrimation and coughing are only induced at a much higher concentrations (OECD, 2005).

Concentrations of the chemical attained in humans in the upper gastrointestinal tract after consumption of alcoholic beverages can cause local irritation.

The chemical produced irritant effects in several eye irritation studies in rabbits. While the severity of these effects was not consistent across all the studies, these were sufficiently severe in some studies to support classification, particularly under the Globally Harmonised System of Classification and Labelling of Chemicals.

D. Sensitization

The available data indicate that the chemical does not induce skin sensitisation in animals. An ear swelling study was used to examine the skin sensitising potential of ethanol. Ethanol was applied twice on the right ear after an induction procedure involving two scapular subcutaneous injection of adjuvant and multiple topical ethanol applications to the abdomen over a period of 14 days. The degree of contact hypersensitivity is deduced from ear swelling measured 24 and 48 hours after application. Ethanol was found not to cause any statistical increase in ear swelling, in contrast to 3 positive controls which all caused a statistically significant increase.

Data is also available from studies using ethanol as a vehicle. In a guinea pig maximisation study that used ethanol as a carrier solvent for the substance being tested (polyakylene glycol block copolymers) no positive reactions were obtained. It can be concluded that ethanol cannot have any significant skin sensitising properties since it was used as a solvent in this study at levels of up to 75%. A study was carried out to evaluate the effect of vehicles (e.g. ethanol) for use in the mouse local lymph node assay (LLNA), and their influence on the skin sensitization potential of fragrance materials. Groups of mice were treated with each test fragrance in ethanol (1:3 or 3:1 mixtures of the two), or with ethanol alone. Although there were no true control data for comparison with the ethanol-alone treated animals, the level of induced T-lymphocyte proliferation was low for ethanol when compared with that for fragrance materials known to be mild to moderate skin sensitizers, and comparable to other inert vehicles tested.

E. Repeated Dose Toxicity

Oral

Many repeated dose studies of chemical have been conducted in many species, predominantly with the aim of assessing adverse effects associated with the consumption of alcoholic beverages. Consequently, these are mostly conducted through oral exposure and with doses well in excess of those that might be encountered in occupational exposure or consumer products (OECD, 2005), or unintentional public exposures from environmental contamination.

In a 90-day study, SD rats were fed a mixture containing 16.25% USP ethanol at 3 dose levels (Kl =2). A single dose of 4 ml/kg of pure ethanol and water were used as controls. No significant differences were noted in body weight, haematology, opthamology, clinical chemistry or urine chemistry. Dose-related increases in liver to body weight ratios of female rats were seen at final sacrifice although the absolute liver weights of the high dose ethanol treated group, while significantly increased relative to the 100% ethanol treated group, was not different from the water control group. In addition, increased liver weights were observed in the male rats. Significant increases in kidney weights were observed in the mid and high dose groups. No histopathologic findings were attributed to ethanol treatment with exception of increased minimal focal to multifocal renal tubular epithelial hyperplasia in the high dose 20 ml/kg mixture containing 16.25% ethanol and the 100% USP ethanol control treated rats versus the water treated controls. It should be noted however that renal tubular epithelial hyperplasia is a common incidental finding in laboratory rats and it is uncertain whether the higher incidence of this lesion in the ethanol dosed rats compared with water controls is due to a random variation or to ethanol. Gonadal tissues were examined for both gross pathology and histopathology and no treatment-related effects were detected. The NOAEL for the study was determined at 10 ml/Kg for a mixture containing 16.25% ethanol for increased kidney weight and renal tubular epithelial hyperplasia in males (equivalent to 1.73g/kg). The LOAEL for this study was determined at 4 ml/kg for 100% USP ethanol (3.16g/kg) for increased kidney weight and renal tubular epithelial hyperplasia in males.

Inhalation

As properly conducted studies in animals are not available, there are no valid data on the effects of repeated inhalation exposure to the chemical. However, limited information is presented below to indicate that the chemical is likely to be of low toxicity following repeated inhalation exposure.

Dermal

No data are available.

F. Genotoxicity

Overall, ethanol is not considered to be mutagenic or genotoxic (OECD, 2005; REACH).

In Vitro Studies

Table 2: *In vitro* Genotoxicity Studies on Ethanol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	Zeiger et al., 1992
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	2	Wangenheim and Bolcsfoldi, 1988

*+, positive; -, negative;

In Vivo Studies

Several in vivo micronucleus assays have assessed the potential for the chemical to induce damage to chromosomes of erythroblasts. No effect was reported in rats when administered 5 % of the chemical (approximately 4 g/kg bw/day) in drinking water, or in mice at up to 40 % (approximately 31 g/kg bw/day). Chemical-related mortality was observed in the latter study. Marginally statistically significant increases in the incidence of micronucleated bone marrow erythrocytes were reported in rats fed for six weeks with a diet containing ethanol at 12–16 g/kg/day. Although there is very limited evidence that the chemical induces micronuclei in the bone marrow of rodents, the chemical has the potential to induce micronuclei in bone marrow erythrocytes at very high doses. KI scores were not listed for these studies (IMAP, 2014).

G. Carcinogenicity

Oral

A significant number of carcinogenicity studies have been identified, but the majority of these are only partial studies designed to look at aspects of the carcinogenic hazard resulting from drinking ethanol containing beverages and are judged unreliable for assessing the cancer hazard of ethanol as a chemical substance. Only two studies were identified as reliable.

In a study to assess the carcinogenic potential of ethanol, groups of rats were exposed to ethanol at concentrations of 1% and 3% in a liquid semi-synthetic diet for a period of 2 years, approximately equivalent to 1 and 3g/kg respectively. Each dose group used a control matched for caloric content using glucose. From the data it was possible to conclude that ethanol did not cause any treatment related increase in tumours and the no effect level was identified as > 3g/kg.

In a study designed and conducted to determine the long-term toxicity and carcinogenicity of urethane in ethanol, groups of mice were exposed to ethanol at concentrations up to 5% in drinking water for a period of 2 years, with control groups consuming drinking water alone. The only significant cancer finding was a dose related increase in the rate of hepatocellular adenomas for male mice in comparison with the concurrent controls. The species of mouse used in this study is known to have a high spontaneous incidence of these tumours. In comparison to historic controls, the incidence rate in the ethanol dosed animals was not high and the controls were significantly lower (although it should be noted that no historic control information was available for animals on the study diet used.) Analysis of the data using the Benchmark dose approach showed a BMDL10 of 1400mg/kg for liver adenomas in males. There was no significant increase in tumour rates (including mammary tumours) in females.

The International Agency for Research on Cancer (IARC) has concluded that there is sufficient evidence in humans and experimental animals to establish carcinogenicity of alcohol consumption and ethanol, respectively. It was also concluded that there is sufficient evidence in experimental animals to establish carcinogenicity of acetaldehyde (major metabolite of ethanol). Consequently, IARC has classified that 'alcohol consumption is carcinogenic to humans (Group 1)' and that 'ethanol in alcoholic beverages is carcinogenic to humans (Group 1)'. This conclusion was supported by an analysis of the expanded human dataset that carcinogenic effects appeared independent of the type of alcoholic beverage (IARC, 2010; IARC, 2012). As the use of the chemical in alcoholic beverages is not considered in this report, the above assessment of carcinogenicity of alcohol beverages may not be relevant to occupational exposure to the chemical or from using the chemical in consumer products (OECD, 2005). Furthermore, studies in animals conducted mostly through oral exposure at very high doses, exceeding the 'maximum tolerated dose', may be of little relevance when assessing risks associated with occupational exposure or using consumer products containing the chemical (OECD, 2005). Thus, classification as a carcinogen is not considered appropriate (IMAP).

Inhalation

No information available (IMAP, REACH).

H. Reproductive and Developmental Toxicity

The chemical does not show specific reproductive or developmental toxicity. Any reproductive and developmental effects were only observed secondary to maternal toxicity. As results of inhalation studies showed no developmental toxicity from chemical exposures even at maternally toxic doses, it can be concluded that deliberate oral consumption of alcoholic beverages is required for any reproductive or developmental toxicity (OECD, 2005).

The most reliable study (Kl = 1) performed to the most appropriate protocol and the one given the greatest weight as well as the key study is a two-generation study investigated the effects of 5%, 10% and 15% ethanol in drinking water in reproduction and fertility. Male and female CD-1 mice were continuously treated for 1 week prior to mating and for a 14-week breeding period followed by a 21-day holding period when they were separated and housed individually. The F1 offspring of the 15% ethanol pairs had fewer live pups per litter but ethanol treatment had no effect on the proportion of breeding pairs producing at least 1 litter during the continuous breeding phase or the number of litters per pair. The F1 offspring from the 15% group had decreased bodyweight at weaning and mating, and a decreased weight of testis, epididymides and seminal vesicles which was no longer evident when these were adjusted for body weight. There was also a significantly decreased percentage motile sperm but no changes in sperm concentration, and percentage of abnormal sperm or tailless sperm. When reproductive performance of F1 control and 15% ethanol-treated breeding pairs was assessed at 74 days of age, there was no significant difference in mating and fertility between the groups. However, adjusted live pup weight for the ethanol group was significantly reduced compared to controls which was likely due to generalized maternal toxicity.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ethanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is 1,730 mg/kg-day based on increased relative and absolute liver weight and absolute heart, liver, kidney and lung weight in male mice from a 90-day dietary study (1996). The NOAEL of 1,730 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD):

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 1730/(10 x 10 x 1 x 3 x 1) = 1730/300 = 6 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (6 x 70 x 0.1)/2 = 21 mg/L

B. Cancer

Evidence of the carcinogenicity of ethanol is confined to epidemiological studies assessing the impact of alcoholic beverage consumption. These do not indicate any such hazard exists from potential exposure to ethanol in the workplace or from the use of ethanol in consumer products (OECD, 2004). Therefore, no cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ethanol is a flammable liquid.

Ethanol does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute aquatic toxicity ranges from 275 to 15,300 mg/L, depending on species and exposure durations. While chronic toxicity ranges from 9.6 to 250 mg/L.

B. Aquatic Toxicity

<u>Acute Studies</u>

Table 3 lists the results of acute aquatic toxicity studies conducted on ethanol.

Table 3: Acute Aquatic Toxicity Studies on Ethanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hr LC_{50}	15,300	2	ECHA
Pimephales promelas	96-hr LC_{50}	14,200	2	ECHA
Ceriodaphnia dubai	48-hr EC_{50}	5012	2	ECHA
Chlorella vulgaris	72-hr EC_{50}	275	2	ECHA

Chronic Studies

The 5-d NOEC to *Brachydanio rerio* in an OECD 212 embryo and sac-fry stage test is 250 mg/L (ECHA) [Kl. score = 2].

The 10-d NOEC to *Ceriodaphnia dubia* in a *Daphnia* reproduction test is 9.6 mg/L (ECHA) [Kl. score = 2].

The 72-hr EC_{10} to algae *Chlorella vulgaris* is 11.5 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for ethanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (14,200 mg/L), invertebrates (5,012 mg/L), and algae (275 mg/L). Results from chronic studies are available for fish (250 mg/L), invertebrates (9.6 mg/L), and algae (11.5 mg/L). On the basis that the data consists of short- and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC or EC_{10} value of 9.6 mg/L for invertebrates. The $PNEC_{aquatic}$ is 0.96 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The PNECsoil is 0.013 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.02/1500) \times 1000 \times 0.96$
$= 0.013$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1.05 \times 0.02$
$= 0.02$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethanol based on the molecular connectivity index (MCI) is 1.05 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ethanol is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -0.35, ethanol does not meet the screening criteria for bioaccumulation.

No chronic aquatic toxicity studies are available on ethanol. The acute $E(L)C_{50}$ values for ethanol are >1 mg/L. Thus, ethanol does not meet the criteria for toxicity.

Therefore, ethanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable liquid, Category 2
Eye irritation, Category 2B
Acute Toxicity, Category 3
Reproductive toxicity, Category 2

Specific target organ toxicity – Repeated exposure, Category 2
Specific target organ toxicity – Single exposure, Category 3

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Protect unexposed eye. Rinse/ flush exposed eye(s)s gently using water for 15-20 minutes. Remove contact lens(es) if able to do so during rinsing. Seek medical attention if irritation persists or if concerned.

Skin Contact
Wash affected area with soap and water. Rinse thoroughly. Seek medical attention if irritation, discomfort, or vomiting persists.

Inhalation
Move exposed individual to fresh air. Loosen clothing as necessary and position individual in a comfortable position. Seek medical advice if irritation persists.

Ingestion
Rinse mouth thoroughly. Do not induce vomiting. Have exposed individual drink sips of water. Seek medical attention if irritation, discomfort, or vomiting persists.

B. Fire Fighting Information

Extinguishing Media

For small fires, use dry chemicals, CO_2, water spray or alcohol-resistant foam. For large fire, use water fog or alcohol-resistant foam. Use appropriate fire suppression agents for adjacent combustible materials or sources of ignition.

Specific Exposure Hazards
Combustion products may include carbon oxides or other toxic vapors. Dangerous fire hazard when exposed to hear, sparks, and open flames.

Special Protective Equipment for Firefighters
Wear protective equipment. Use NIOSH-approved respiratory protection/ breathing apparatus. Use spark-proof tools and explosion-proof equipment. Move product containers away from fire or keep cool with water spray as a protective measure, where feasible.

C. Accidental Release Measures

Personal Precautions
Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas. Keep unprotected persons away.
Wear protective equipment. Use respiratory protective device against the effects of fumes/ dust/ aerosol. Ensure adequate ventilation. Keep away from ignition sources. Protect from heat.
For large spills, wear splash goggles, full suit, respirator, boots and gloves and use self-contained breathing apparatus.

Environmental Precautions
Prevent from reaching drains, sewer, or waterway. Collect contaminated soil for characterisation. Collect spilled liquid for recovery, treatment, or disposal.

Steps to be Taken if Material is Released or Spilled
Eliminate sources of ignition. Stop the spill, if possible. Contain spill material by diking or using inert absorbent. Spill may also be contained by using electrically protected vacuum cleaner or by wet-brushing. Transfer to a disposal or recovery container.

D. Storage And Handling

General Handling
Prevent formation of aerosols. Use only in well ventilated areas. Avoid splashes or spray in enclosed areas. Prevent exposure to ignition sources; use non-sparking tools and explosion-proof equipment.

Other Handling Precautions

Avoid contact with eyes, skin, and clothing. Avoid breathing vapor. Follow good hygiene procedures when handling chemical materials. Do not eat, drink, smoke, or use personal products when handling substances. Wash hands before breaks and at the end of work.

Storage

Store in a cool location. Provide ventilation for containers. Avoid storage near extreme heat, ignition sources, or open flame. Store away from foodstuffs. Store away from oxidizing agents. Store in cool, dry conditions in well-sealed containers. Keep containers tightly sealed. Store in secure flammable storage area away from sources of ignition. Protect from freezing and physical damage.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for ethanol in Australia is 1000 ppm (1880 mg/m^3) as an 8-hr TWA. No STEL is listed.

Engineering Controls

Good general ventilation should be used. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. Avoid storage near extreme heat, ignition sources, or open flame. Use non-sparking tools and explosion-proof equipment.

Personal Protection Equipment

Respiratory Protection: Not required under normal conditions of use. Use suitable respiratory protective device when high concentrations are present. Use suitable respiratory protective devise when aerosol mist is formed. For spills, respiratory protection may be advisable.

Hand Protection: Gloves that are impermeable and resistant to the substance

Skin Protection: Wear chemical resistant gloves (rubber, neoprene or vinyl). Use personal protection equipment that is chemical resistant and prevents skin contact.

Eye protection: Goggles or safety glasses with side shields

Other Precautions:

- Use other PPE as required by the situation.
- Ethanol is a flammable liquid; keep away from ignition sources. Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period.
- Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing.

- Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN Number: 1170
UN proper shipping name: Ethanol (mixture)

Transport hazard class: 3 Flammable liquids
Packing group: II

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Inventory Multi-Tiered assessment and prioritization [IMAP] (2014). Human health Tier 2 assessment for ethanol. Australian Government, Department of Health, National Industrial Chemicals Notification and Assessment Scheme.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ETHOXYLATED BRANCHED C13 ALCOHOL
[ISOTRIDECANOL, ETHOXYLATED]

This dossier on isotridecanol, ethoxylated presents the most critical studies pertinent to the risk assessment of isotridecanol, ethoxylated in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the Human & Environmental Risk Assessment on Ingredients of European Household Cleaning Products: Alcohol Ethoxylates (HERA, 2009). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Isotridecanol, ethoxylated

CAS RN: 69011-36-5

Molecular formula: Not available (UVCB substance)

Molecular weight: Not available (UVCB substance)

Synonyms: Isotridecanol, ethoxylated; C13 ethoxylated alcohol; Alcohol C13 ethoxylated; ethoxylated branched C13 alcohol

SMILES: Not available (UVCB substance)

Alcohol ethoxylates (AE) are a class of non-ionic surfactants that have the basic structure $C_{x\text{-}y}AE_n$. The subscript (x-y) following the 'C' indicates the range of carbon chain units. The hydrocarbon chain can be either linear or branched. AEs also contain an ethylene oxide (E) chain attached to the alcohol. The degree of ethylene oxide polymerization is indicated by the subscript (n) which indicates the average number of ethylene oxide units. Isotridecanol, ethoxylated (CAS No. 69011-36-5) has an average number of 1 to 2.5 moles of ethylene oxide units.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Isotridecanol, ethoxylated (1 to 2.5 moles ethoxylated)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancy odor	2	ECHA
Melting Point	-11.6°C	1	ECHA
Boiling Point	>280°C	1	ECHA

Property	Value	Klimisch score	Reference
Density	0.907 g/cm^3 @ 20°C	1	ECHA
Vapor Pressure	<5 Pa @ 20°C	2	ECHA
Partition coefficient (log K_{ow})	4.9* (calculated)	2	ECHA
Water Solubility	20-29 mg/L @ 21°C	1	ECHA
Flash Point	138°C @ 1013 hPa	1	ECHA
Auto flammability	250°C @ 1015 hPa	1	ECHA
Viscosity	38.2 mm^2/s (static) @ 20°C	1	ECHA

*Weight-averaged log K_{oc} of whole substance based on normalized composition

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Isotridecanol, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

Isotridecanol, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 75% in 28 days (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
Using KOCWIN v2.00, the following calculated K_{oc} values were obtained: 441.7 for alcohol, C13, branched; 359.3 for alcohol ethoxylate, C13, branched, 1 EO; and 237.8 for alcohol ethoxylate, C13, branched, 3 EO (ECHA).

The average of the K_{oc} values for the C13 ethoxylated alcohols, which is 298.6 L/kg, will be used to calculate the PNEC values for sediment and soil.

D. Bioaccumulation

There are no bioaccumulation studies on this substance. It is not expected to bioaccumulate based on its estimated log Kow (ECHA).

E. Bioaccumulation

The BCF values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of isotridecanol, ethoxylates is low by the oral and dermal routes. The skin irritation rabbit studies on isotridecanol, ethoxylated and similar alcohol ethoxylates show that the degree of irritation depends on the testing conditions and length of the exposure period. Human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Isotridecanol, ethoxylated with EO units of 1 to <2.5 are not irritating to the eyes of rabbits. Isotridecanol, ethoxylated is not a skin sensitizer. Repeated dose toxicity studies on alcohol ethoxylates similar to isotridecanol, ethoxylates in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic, and have a low potential for reproductive and developmental toxicity.

B. Acute Toxicity

No acute toxicity studies are available on isotridecanol, ethoxylated.

The oral LD_{50} in rats for $C_{12\text{-}13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_{7}$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2].

There are no acute inhalation toxicity studies on isotridecanol, ethoxylated.

An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_{3}$ and $C_{12\text{-}14}AE_{6}$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_{7}$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, branched, ethoxylated (3-4 EO) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) to the skin of rabbits for 24 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL alcohols C12-13, branched and linear, <2.5 EO to the skin of rabbits for 4 hours under occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or edema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2].

Eye

Instillation of 0.1 mL isotridecanol, ethoxylated (3 EO) (CAS No. 69011-36-5) into the eyes of rabbits was severely irritating. The means of the 24, 48, and 72 hour scores were: 1.6 for corneal opacity; 0.6 for iridial lesions; 2.2 for conjunctival redness; and 0.7 for chemosis. The effects were not fully reversible within 21 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL isotridecanol, branched, ethoxylated (3-4 EO) (CAS No. 24938-91-8) into the eyes of rabbits was severely irritating. The means of the 24, 48, and 72 hour scores were: 1.0 for corneal opacity; 0.1 for iridial lesions; 1.7 for conjunctival redness; and 0.6 for chemosis. The effects were not fully reversible within 8 days (ECHA) [Kl. score = 2].

Instillation of 0.1 mL alcohols C12-13, branched and linear, <2.5 EO (CAS No. 160901-19-9) into the eyes of rabbits was not irritating. The means of the 24, 48, and 72 hour scores were: 0.00 for corneal opacity; 0.00 for iridial lesions; 0.83 for conjunctival redness; and 0.50 for chemosis (ECHA) [Kl. score = 2].

Instillation of 0.1 mL $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) into the eyes of rabbits was not irritating. The mean of the 24, 48, and 72 hour scores were: 0.00 for all endpoints (ECHA) [Kl. score = 2].

D. Sensitization

No sensitization studies are available on isotridecanol, ethoxylated.

In a guinea pig maximization test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitizer (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

No repeated dose toxicity studies are available on isotridecanol, ethoxylated.

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125, 0.25, 0.5 or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the $\geq$0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights

were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12-14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12-13}AE_{6.5}$ for two years. Body weight gain was reduced in the 1% males and ≥0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the ≥0.5% females (liver, kidney and brain), 1% females (heart), and 1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidence in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
No adequate studies are available.

F. Genotoxicity

In Vitro Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to isotridecanol, ethoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14-15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In Vivo Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50, or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009) [Kl. score = 2].

G. Carcinogenicity

No studies are available on isotridecanol, ethoxylated.

Male and female Sprague-Dawley rats were given in their diet $C_{12\text{-}13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumor incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behavior and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumor incidence (HERA, 2009) [Kl. score = 2]

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

No studies are available on isotridecanol, ethoxylated.

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behavior, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0, 0.05, 0.1 or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behavior or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

No studies are available on isotridecanol, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behavior, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean fetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE_6$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live fetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for isotridecanol, ethoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A two-year dietary study in rats has been conducted on $C_{12\text{-}13}AE_{6.5}$ (HERA, 2009). The NOAEL from this study is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for isotridecanol, ethoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

The alcohol ethoxylates $C_{12\text{-}13}AE_{6.5}$ and $C_{14\text{-}15}AE_7$ were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Isotridecanol, ethoxylated does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Isotridecanol, ethoxylated has moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC, 2000), the toxicity data was normalized for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalized to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 μg/L.

Freshwater crustaceans: 2 species, 590 to 860 μg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 μg/L

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 μg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320, and 330 μg/L, although replication was insufficient to meet OECD (1992) requirements. Normalized data were 380, 380, 320, and 1,520 μg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

$PNEC_{water}$: The ANZECC water quality guideline (2000) for freshwater is: **"A high reliability trigger value of 140 μg/L was derived for AE (normalized data) using the statistical distribution method with 95% protection."**

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.71 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (6.53/1280) \times 1000 \times 0.14$
$= 0.71$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times (Kp_{sed}/1000) \times BD_{solid}]$
$= 0.8 + [0.2 \times (11.94/1000) \times 2400]$
$= 6.53$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 298.6 \times 0.04$
$= 11.94$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for isotridecanol, ethoxylated is 298.6 (see section III.C)

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.56 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (5.97/1500) \times 1000 \times 0.14$
$= 0.56$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 298.6 \times 0.02$
$= 5.97$

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for isotridecanol, ethoxylated is 298.6 (see section III.C)
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Isotridecanol, ethoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The bioconcentration factors (BCF) in fish for ethoxylated alcohols (which includes isotridecanol, ethoxylated) have been reported to range from <5 to 387.5. Thus, isotridecanol, ethoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, isotridecanol, ethoxylated alcohol does not meet the criteria for toxicity.

The overall conclusion is that isotridecanol, ethoxylated is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Eye Irritant Category 2
Aquatic Chronic Toxicity Category 3

B. Labelling

Danger
According to the classification provided by companies to ECHA in CLP notifications this substance is very toxic to aquatic life, causes serious eye damage, is harmful if swallowed, is harmful to aquatic life with long lasting effects and causes skin irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions
Prevent from entering sewers, waterways, or low area

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for isotridecanol, ethoxylated.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Wear respiratory protection if ventilation is inadequate.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Chemical safety goggles.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Isotridecanol, ethoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

ETHYLENE GLYCOL

This dossier on ethylene glycol presents the most critical studies pertinent to the risk assessment of ethylene glycol in its use in hydraulic fracturing fluids. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ethane-1,2-diol

CAS RN: 107-21-1

Molecular formula: $C_2H_6O_2$ ($HOCH_2CH_2OH$)

Molecular weight: 62.07 g/mol

Synonyms: Ethylene glycol; ethane-1,2-diol; 1,2-ethanediol, 2-hydroxyethanol; monoethylene glycol; MEG; glycol alcohol; EG

SMILES: C(CO)O

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Ethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20oC and 101.3 kPa	Colourless and odourless syrupy liquid	2	ECHA
Melting Point	-13°C @ 101.3 kPa	2	ECHA
Boiling Point	197.4°C @ 101.3 kPa	2	ECHA
Density	1110 kg/m3@ 20°C	2	ECHA
Vapour Pressure	12.3 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-1.36 (calculated) @ 25°C	2	ECHA
Water Solubility	1000 g/L @ 20°C	2	ECHA
Flash Point	111°C	2	ECHA
Auto flammability	398°C	2	ECHA
Viscosity	16.1 mPa s @ 25°C	2	ECHA
Henry's Law Constant	0.133 @ 25°C (QSAR)	2	ECHA

III. ENVIRONMENTAL FATE SUMMARY

A. Summary

Ethylene glycol is readily biodegradable, and it is not expected to bioaccumulate. Ethylene glycol has low potential to adsorb to soil and sediment.

B. Biodegradation

Ethylene glycol was readily biodegradable in an OECD 301A test. After 10 days, degradation was 90-100% (ECHA) [Kl. score = 1]. There was 97% degradation after 20 days in a BOD test; and 96% degradation after 28 days in an OECD 301D test (Waggy et al., 1994; OECD, 2004a,b) [Kl. score = 2]. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

The aerobic degradation of ethylene glycol was measured from grab river water samples at 4, 8 and 20°C. At 20°C, ethylene glycol was completely degraded in three days in all river waters tested; at 8°C, degradation was complete within 14 days. Degradation at 4°C was substantially slower, with degradation of < 20% after 14 days in river samples with limited suspended matter and a starting concentration of 10 mg/L (Evans and David, 1974).

C. Environmental Distribution

No experimental data are available for ethylene glycol. Using KOCWIN in EPISuite™ (USEPA, 2017), the estimated K_{oc} values from the molecular connectivity index (MCI) and from the log K_{ow} are 1 and 0.2239 L/kg, respectively.

Based upon these K_{oc} values, if released to soil, ethylene glycol is expected to have low potential for adsorption and a high potential for mobility. If released to water, based on its K_{oc} and high water solubility values, ethylene glycol is likely to remain in water and not adsorb to sediment. From the water surface, the substance will not evaporate into the atmosphere (ECHA).

D. Bioaccumulation

The calculated log K_{ow} for ethylene glycol is -1.36 (ECHA). The BCF for ethylene glycol in golden ide (*Leuciscus idus melanotus*) after three days of exposure was determined to be 10 (Freitag *et al.*, 1985). Bioaccumulation is not to be expected.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity. The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg. Ethylene glycol is not a skin irritant or a skin sensitiser in laboratory animals. In humans, ethylene glycol may cause skin irritation; there is also a low potential for skin sensitisation. It is not an eye irritant. The kidney is the primary target organ from repeated exposures. The proposed mode-of-action (MOA) for the kidney damage involves the formation of a precipitate or crystals from the ethylene glycol metabolite oxalic acid with calcium in the urine. Ethylene glycol is not genotoxic or carcinogenic to rodents. Ethylene glycol did not affect fertility in animal studies, but it did cause developmental effects. In rodents, the

developmental effects caused by oral doses of ethylene glycol include teratogenic effects (craniofacial and axial-skeletal malformations and variations). In contrast, no developmental toxicity was seen in rabbit studies. The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits. Based on a physiologically-based pharmacokinetic (PBPK) model for ethylene glycol, humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity.

B. Metabolism

Ethylene glycol is almost completely absorbed in laboratory animals by the oral route (OECD, 2004a; Frantz et al., 1996a). A range of 1-51% of ethylene glycol is absorbed by the dermal route based on *in vivo* studies in rodents (Frantz et al., 1996a,b).

The main metabolic pathway for metabolism of ethylene glycol is oxidation via alcohol dehydrogenases and aldehyde dehydrogenases. The main metabolites of ethylene glycol are carbon dioxide, oxalic acid and glycolic acid (OECD, 2004a).

The relevant metabolite for the repeated dose toxicity studies is oxalic acid, which is slowly transported from the liver to the kidneys, where is forms calcium-oxalate crystals (Corley et al., 2005a).

The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits (Carney et al., 1998).

A physiologically-based pharmacokinetic (PBPK) model has been developed for ethylene glycol. When internal dose surrogates were compared in rats and humans over a wide range of exposures, it has been concluded that humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity (Corley et al., 2005b).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,712 mg/kg (ECHA) [Kl. score = 2]. The 6-hour inhalation LC_{50} value for male and female rats was > 2.5 mg/L (Tyl et al., 1995a) [Kl. score = 2]. The dermal LD_{50} for male and female mice is > 3,500 mg/kg (Tyl et al., 1995b) [Kl. score = 2].

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity (ECHA). The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg (Hess et al., 2004).

D. Irritation

Application of 0.5 mL of ethylene glycol to the skin of rabbits for 23 hours under occlusive conditions was not irritating (Guillot et al., 1982) [Kl. score = 2].

In a Human Repeated Insult Patch Test (HRIPT), ethylene glycol was applied to the skin for 24 hours under occlusive or semi-occlusive conditions for nine times during the induction phase. The induction phase was followed by a rest period of two weeks, followed by a 24-hour challenge on the sixth week of the study. Erythema was seen in a small proportion of the 401 subjects that completed the study. Under the conditions of the study, three subjects had reactions on challenge that were

indicative of possible irritation and/or low-level sensitisation. These three subjects were re-challenged under occlusive or semi-occlusive conditions one or two weeks later. Re-challenge testing was negative for one subject, but the other two subjects were judged to have irritant reactions to ethylene glycol since their reactions were similar or lesser compared to the skin responses observed during the induction period, and the skin reactions were not greater over time after the challenge or re-challenge (ECHA).

Instillation of 0.05 mL of ethylene glycol into the eyes of rabbits was not irritating (ECHA) [Kl. score = 2].

E. Sensitisation

Ethylene glycol was not a skin sensitiser to guinea pigs in a Magnusson and Kligman test (Kurihara et al., 1996) [Kl. score = 2]. In a HRIPT, ethylene glycol was considered to have a low potential for dermal sensitisation in humans (ECHA).

F. Repeated Dose Toxicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5% ethylene glycol for 13 weeks. Mortality was seen in the 5% males, but not in females. Mean weight gain was significantly decreased in the 2.5 and 5% males; there was no significant differences in female rats. Feed consumption was similar across all groups. A significant increase was seen in the left kidney weight in the 2.5 and 5% dose groups (both sexes); this was not seen in the right kidneys. Mean thymus ratio to terminal body weight was significantly decreased in the 5% males. Serum urea nitrogen levels were significantly increased in the 2.5 and 5% males, and significantly increased in the ≥ 0.32% females. Creatinine levels were decreased in the 0.32% groups and significantly increased in the 2.5 and 5% groups. The 2.5% and 5% male rats had kidneys that were rough, granular and/or pitted appearances. The 5% females showed nephrosis, and the 5% males had clusters of crystals in the brain. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2]

Male and female Sprague Dawley rats were given in their drinking water ethylene glycol for 90 days. The concentrations for females were 0, 0.5, 1.0, 2.0 or 4.0% (0, 597, 1,145, 3,087 or 5,744 mg/kg/day). The concentrations for males were 0, 0.25, 0.5, 1.0 or 2.0% (0, 205, 407, 947 or 3,134 mg/kg/day). In the 4% groups, there was mortality and decreased body weights (males only). Significant organ weights were noted only in males. Kidney weights were significantly increased in the 1% and 2% males; heart, liver and lung were significantly decreased in the 2% males. The 4% males also had a significant increase in the brain and gonads relative to body weights. Leukocyte levels were significantly decreased in the 0.5, 2 and 4% females, but not in males. Significant differences were noted in LDH, creatinine, ALT, calcium and glucose in the 1% males; and phosphorus, BUN and creatinine in the 2% males. There were significant increases in phosphorus in the 1% females and glucose in the 0.5 and 4% females. Kidney lesions were seen in the ≥ 2% females and in the ≥ 1% males, with the lesions more prominent in males than in females. The kidney changes consisted of tubular dilation, tubular degeneration, acute inflammation, birefringent crystals in tubules and pelvic epithelium. The NOAEL for this study is 407 mg/kg/day for males. The LOAEL for females is 597 mg/kg/day; a NOAEL was not established (Robinson et al., 1990) [Kl. score = 2]

Male and female B6C3F$_1$ mice were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5.0% ethylene glycol for 13 weeks. There was no mortality and no treatment-related effect on mean weight gain and feed consumption. Organ/body weight ratios were similar across all groups. Serum urea nitrogen and creatinine levels were unaffected. Kidney effects were seen in the male, but not female, mice. Kidney lesions were observed in half of the 5% male mice and one mouse in the 2.5% dose level. Lesions were tubular dilation, cytoplasmic vacuolisation and regenerative hyperplasia of tubular cells. There was no evidence of crystal formation in the tubules. These changes were focal, randomly distributed and of minimal to mild severity. Hyaline degenerative of the liver was present in the centrilobular hepatocytes in all of the 2.5% and 5% males. These cells showed cytoplasmic accumulations of non bifringent, eosinophilic (hyaline), globular or crystalline material which resembled erythrocytes in size, shape and tinctorial properties. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2].

Male Fischer 344 and Wistar rats were given in their feed 0, 150, 500 or 1,000 mg/kg ethylene glycol for 16 weeks. At 1000 mg/kg, the following effects were seen: mortality in Wistar strain (2/10) with prior clinical observations of emaciation and dermal atonia and macroscopic findings of changes in kidneys (pale, calculi) and small seminal vesicles in these animals; mean body weight losses, lower mean body weights and mean cumulative body weight changes in Wistar strain (weeks 2 – 16); lower mean food consumption in Wistar strain; higher mean water consumption in both F344 and Wistar strains; lower mean specific gravity and higher mean total urine volume in both F344 and Wistar strains; macroscopic findings of pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weights in both F344 and Wistar strains; renal macroscopic findings of crystal nephropathy in Wistar and F-344 rats, with more severe nephropathy in Wistar strain than in the F344 strain. At 500 mg/kg, the following effects were seen: lower mean body weights (study weeks 3, 6-8 and 10-12) and mean cumulative body weight changes in the Wistar strain throughout the study with slightly lower mean food consumption throughout the study; higher mean water consumption in the Wistar strain; lower mean urine specific gravity and higher mean total urine volume in the Wistar strain; macroscopic findings in the Wistar strain consisting of predominantly pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weight in the Wistar strain; renal macroscopic findings of crystal nephropathy in Wistar and F-344 strains, with more severe nephropathy in the Wistar strain than in the F344 strain. The NOAEL in both the F344 and Wistar rats is 150 mg/kg/day (Cruzan et al., 2004) [Kl. score = 2].

Male Wistar rats were given in their feed 0, 50, 150, 300 or 400 mg/kg ethylene glycol for 12 months. There was mortality in the 300 and 400 mg/kg dose groups (5/20 and 4/20, respectively); the remaining 400 mg/kg animals were euthanised early (Day 203) due to excessive weight loss. The 300 mg/kg animals had increased water consumption and urine volume with decreased specific gravity, most likely due to osmotic diuresis. Calculi (calcium oxalate crystals) were found in the bladder and kidney pelvis in the ≥ 300 mg/kg animals. The ≥ 300 mg/kg rats that died prematurely had transitional cell hyperplasia with inflammation and haemorrhage of the bladder wall. Crystal nephropathy (basophilic foci, tubule or pelvic dilatation, birefringent crystals in the pelvic fornix, or transitional cell hyperplasia) was seen in all of the 400 mg/kg and most of the 300 mg/kg rats. These effects were not seen in the 50 or 150 mg/kg rats. Kidney oxalate levels, the metabolite responsible for the kidney toxicity, was not increased in the 50 and 150 mg/kg animals compared to the controls. The NOAEL for this study is 150 mg/kg/day (Corley et al., 2005) [Kl. score = 1].

Male and female Sprague-Dawley rats were given in their feed 0, 0.1, 0.2, 0.5, 1.0 or 4.0% ethylene glycol for two years. There was significant reduction in growth in the 4% males after week 16, and in the 1% males after week 70. The 4% females did not gain any weight past the first year of the study. Water consumption was double that of the controls in the 4% males that initiated soon after the

start of the study. The 1% males had significant increases in water consumption after 6 months and some increase was observed in the 0.5% males. Females only showed increased water consumption in the 4% group. There was 100% mortality in the 1 and 4% males, while mortality of additional dose levels were below that of the controls. There was 100% mortality in the 4% females, while the 1% females were similar to the controls; the 0.1, 0.2 and 0.5% females were increased compared to the controls. Since the 1 and 4% males and the 4% females all died before the study termination date, there are no data for these groups on terminal organ weight. For males, the terminal organ weights were decreased in all dose levels compared to the controls. For females, the organ weights were similar to the controls. The 1 and 4% males and females had kidneys with stones and crystals. The NOAEL for this study is 0.2% (data was insufficient to calculate the dose) (Blood, 1965) [Kl. score = 2].

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There were numerous adverse effects in the 1,000 mg/kg males and, to a lesser degree, in the 1,000 mg/kg females. The most remarkable effect was the production of urinary calculi in the kidneys, ureters and urinary bladders of the 1,000 mg/kg males, along with the presence of high levels of calcium oxalate in the urine. Increased incidences of tubular cell hyperplasia, tubular dilation, peritubular nephritis and focal granulomatous nephritis occurred in the 1,000 mg/kg males. Other significant findings in these males were markedly lower body weight gain, increased absolute and relative kidney weights, decreased absolute and relative liver weights, various hematopoietic changes and increased water consumption (likely a result of impaired kidney function). Histopathological changes in the 1,000 mg/kg males were mineralisation of the heart, lungs, stomach and vas deferens being the most noteworthy. The various adverse effects in these males resulted in reduced survival; there was increased mortality which became apparent by 8 months, with all males in this group died by month 16. Although calcium oxalate crystals were found in the urine of the 1,000 mg/kg females, no urinary calculi were seen. Absolute and relative kidney weights were increased in these rats. The most significant histopathologic finding in the 1,000 mg/kg females was fatty metamorphosis of the liver. There were transient changes in organ weights, erythroid parameters, water consumption rates and urine specific gravity in the 200 and 40 mg/kg rats; these effects were considered to be statistical artifacts attributable to chance. Focal soft mineralisation was observed in certain organs of the 200 and 40 mg/kg rats, which were considered to be the result of altered calcium metabolism associated with ingestion of ethylene glycol. The NOAEL for this study is considered to be 200 mg/kg/day (DePass et al., 1986a; ECHA) [Kl. score = 2].

Male and female B6C3F_1 mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) for 103 weeks. These concentrations are approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Survival, mean body weights and feed consumption was similar across all groups. There were no treatment-related clinical signs of toxicity. Liver lesions (males only) and arterial hyperplasia (females only) were observed at 12,500 ppm, but no adverse effects were observed at 6,250 ppm. The NOAEL for this study is 6,250 ppm in males, which corresponds to 1,500 mg/kg/day (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies in rodents or rabbits are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on ethylene glycol are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Ethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	+/-	-	2	McGregor et al. (1991)
Chromosomal aberration (CHO cells)	-	-	2	ECHA

*+, positive; -, negative

In Vivo Studies

A dominant lethal study was conducted in F344 rats given 0, 40, 200 or 1,000 mg/kg/day ethylene glycol in feed. There were slight increases in the dominant lethal mutation index in the high-dose and low-dose groups; these appear to be random occurrences and were not considered to be treatment-related. It was concluded that ethylene glycol was not genotoxic in this study (DePass et al., 1986b) [Kl. score = 2].

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There was increased mortality in the 1,000 mg/kg males, starting at 8 months and resulting in all males in this group dead by 16 months. Survival for the 1,000 mg/kg females and the 200 and 40 mg/kg males and females were similar to the controls. The incidence of mononuclear cell leukemia was statistically significantly higher in the 200 mg/kg males compared to the male controls, but not when compared to the pooled controls (males and females). Evaluation of the data by the method of Thomas et al. (2007), however, showed no treatment-related effect. It was concluded that ethylene glycol was not carcinogenic to rats in this study (DePass et al., 1986) [Kl. score = 2].

Male and female $B6C3F_1$ mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) ethylene glycol. These concentrations were approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Body weights, survival and incidence of tumours were similar between treated and control mice (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

I. Reproductive Toxicity

Ethylene glycol was assessed in a Reproductive Assessment by Continuous Breeding (RACB) protocol (Chapin and Sloane, 1997). The parental mice were administered ethylene glycol via drinking water during pre-mating exposure, cohabitation, pregnancy and lactation. The F_1 generation received prenatal exposure via maternal exposure during gestation, with the exposure continuing during lactation, weaning and mating of F_1 animals and production of an F_2 litter. The doses were 0, 0.25, 0.5 or 1% ethylene glycol, which corresponded to approximately 0, 410, 840 or 1,640 mg/kg/day. No adverse effects were noted in the parental animals at doses up to 1%. There was a small, but statistically significant, effects on the numbers of litters per fertile pair, the number of live pups per litter, and live pup weight in the 1% dose group. Neither the 0.25 nor 0.5% dose groups were significantly affected. The number of live pups per litter was lower in the treated groups, but differences were not statistically significant. Unusual facial features (i.e., shorter snout and wide-set eye) and skeletal defects (shortened frontal, nasal and parietal bones; fused ribs abnormally shaped or missing sternebrae, abnormally shaped vertebrae; and twisting of the spine) were noted on some of the offspring of the treated mice in the 1% group, but not in the controls. The parental NOAEL is 1% (approximately 1,640 mg/kg/day), and the NOAEL for reproductive toxicity is 0.5% (approximately 840 mg/kg/day (Lamb et al., 1985) [Kl. score = 2].

In a three-generation reproductive toxicity study, Fischer 344 rats were given in their diet 0, 40, 200 or 1,000 mg/kg/day ethylene glycol. There were no treatment-related effects on clinical signs of toxicity or survival in the parental animals. There were no significant effects on fertility index, gestation index, gestation survival for all three generations. Mean pup weights for each of the hree generations were similar between treated and control animals. The NOAEL for parental and reproductive toxicity is 1,000 mg/kg/day (DePass et al., 1986b) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Sprague-Dawley rats were dosed by oral gavage with 0, 50, 150, 500, 1,000 or 2,500 mg/kg ethylene glycol during gestational days (GD) 6-15. Maternal toxicity was observed in the 2,500 mg/kg group and consisted of significantly decreased body weights, increased water consumption, decreased uterine weights, increased kidney weights and increased relative liver weights. At 500 mg/kg, there were developmental effects, which included reduced foetal body weights, extra or missing ribs, missing arches and poor ossification in thoracic and lumbar centra. In the 2,500 mg/kg group, in addition to skeletal malformations, there was gastroschisis, hydrocephaly, lateral ventricle dilated (tissue depressed), umbilical hernia and atelectasis. The NOAELs for maternal and developmental toxicity are 1,000 and 500 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD rats were dosed by oral gavage with 0, 1,250 2,500 or 5,000 mg/kg ethylene glycol during GD 6-15. In the ≥ 2,500 mg/kg groups, the dams had increased relative kidney weights, decreased gravid uterine weight and increased water consumption. Maternal body weight gain was significantly decreased in the 1,250 mg/kg group. Live litter size was significantly decreased in the 5,000 mg/kg group and foetal body weights were decreased in the 1,250 and 5,000 mg/kg groups. Litters with malformed foetuses were observed in the ≥ 1,250 mg/kg groups. The LOAELs for maternal and developmental toxicity are 1,250 mg/kg/day; NOAELs were not established (Price et al., 1985) [Kl. score = 2].

Pregnant Fischer 344 rats were given by oral gavage 0, 40, 200 or 1,000 mg/kg ethylene glycol during GD 6-15. No maternal toxicity was observed at any dose level. There were no significant effects on preimplantation loss, foetal length, foetal weight, total implantations or litter size. There was an increased incidence of skeletal alterations in the 1,000 mg/kg group, which consisted of poorly ossified and unossified vertebral centra. No significant increases in the incidence of major malformations were observed. The NOAELs for maternal and developmental toxicity are 1,000 and 400 mg/kg/day (Maronpot et al., 1983) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 50, 150, 500 or 1,500 mg/kg ethylene glycol during gestational days (GD) 6 to 15. There was no maternal toxicity. At 1,500 mg/kg, there were reduced foetal body weights, fused ribs and arches, poor ossification in thoracic and lumbar centra and increased occurrence of an extra 14th rib. At 500 mg/kg, there was slight reductions in foetal body weight and increased incidences of extra ribs. The NOAELs for maternal and developmental toxicity were 1,500 and 150 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 750, 1,500 or 3,000 mg/kg ethylene glycol during GD 6 to 15. There was a significant decrease in maternal gain, gravid uterine weights and liver weights in the 1,500 mg/kg group. A decreased number of implantation sites per litter was observed in the 1,500 mg/kg group. Significant decrease in liver litter size was observed in the 3,000 mg/kg group and decreased foetal body weights were seen at ≥ 750 mg/kg. Litters with a significant increase in malformed foetuses were observed in the ≥ 750 mg/kg groups. There was a significant dose-related increase in post-implantation loss per litter, though there were no significant pairwise comparisons. The NOAEL for maternal toxicity is 750 mg/kg/day. The LOAEL for developmental toxicity is 750 mg/kg/day; the NOAEL was not established (Price et al., 1985) [Kl. score = 2].

In a short-term reproductive and developmental toxicity screen test, male and female Swiss Crl:CD-1 mice were allowed to mate over a three-day period. The males were dosed by oral gavage from study Day 3 to study Day 20. The Group A females were exposed throughout the 21-day test period; the Group B females were exposed during GD 8-14. The doses were 0, 250, 700 or 2,500 mg/kg ethylene glycol. The Group A females were sacrificed after 19 days of treatment, and the Group B females were allowed to litter and rear to postnatal day (PND) 4. There was no maternal or paternal toxicity. The 2,500 mg/kg females in Group A had significantly fewer liver implants and more dead implants. The 2,500 mg/kg in Group B had significantly lower total litter weights on PND 1 and 4. The NOAELs for parental and developmental toxicity are 2,500 and 700 mg/kg/day (Harris et al., 1992) [Kl. score = 2].

In a Chernoff/Kavlock assay, pregnant CD-1 mice were dosed by oral gavage with 0 or 11,090 mg/kg ethylene glycol during GD 7-14. The females were allowed to litter and rear to PND 3. Ten percent of the maternal animals died. The number of surviving pups per litter (40% survived), birth weight and pup weight gain were reduced. The LOAELs for maternal and developmental toxicity are 11,090 mg/kg; NOAELs were not established (Schuler et al., 1984; Hardin et al., 1987) [Kl. score = 2].

Pregnant female New Zealand White rabbits were dosed by oral gavage with 0, 100, 500, 1,000 or 2,000 mg/kg ethylene glycol on GD 6 to 19. At 2,000 mg/kg, eight of the 17 does (42.1%) died. Maternal body weights and body weight gain were similar across all groups. There was no developmental toxicity. The NOAEL for maternal toxicity is 1,000 mg/kg/day. The NOAEL for developmental toxicity is 2,000 mg/kg/day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female CD rats were dosed by oral gavage with 0, 250, 1,250 or 2,250 mg/kg ethylene glycol on GD 6 to 20. At 2,250 mg/kg, maternal body weight, body weight gain, kidney weight and postpartum uterine weight were significantly reduced. At 1,250 mg/kg, the gestational period was

lengthened and maternal kidney histopathological effects were noted. Developmental toxicity was noted in the 2,250 mg/kg group and included reduced pup weight, reduced viability and increased malformations (primarily hydrocephaly and abnormalities of the axial skeleton). No developmental toxicity was seen in the 1,250 mg/kg group. The NOAEL for maternal and developmental toxicity is 250 mg/kg/day (ECHA) [Kl. score = 2].

Inhalation

Pregnant female CD rats were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. There was no treatment-related mortality; a dose-related increased in clinical signs (red fur discoloration on the head and neck) was noted, which was considered to be a non-specific indication of stress. Body weights and body weight gain were unaffected by treatment. There was some evidence of treatment-related reductions in ossification of the foetal skeleton at 1,000 and 2,500 mg/m^3 (considered as fetotoxicity). The NOAECs from inhalation exposure cannot be determined due to confounding oral exposure during whole-body exposure. However, there was no maternal or embryotoxicity at 150 mg/m^3 and no teratogenicity at any aerosol concentration tested (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. Reduced maternal body weight was observed in the 2,500 mg/m^3 group on GD 12,15 and 18 and in the 1,000 mg/m^3 group on GD 18. Reduced maternal weight gain was also seen during GD 6-12, 6-15 and GD 6-18 for the ≥ 1000 mg/m^3 groups and for GD 5-18 for the 2,500 mg/m^3 group. Terminal body weights were reduced in the ≥ 1,000 mg/m^3 groups. Gravid uterine weight was also reduced in the ≥ 1,000 mg/m^3 groups, so that body weight corrected for gravid uterine weight was unaffected. The number of viable implantations per litter was reduced at 2,500 mg/m^3. The number of non-viable implantations per litter was elevated at ≥ 1,000 mg/m^3 because of a significant increase in late resorptions at 1,000 mg/m^3, and a significant increase in late resorptions and in dead foetuses at 2,500 mg/m^3. The number of early resorptions at 2,500 mg/m^3 was also elevated but not statistically. foetal body weights per litter (male, female and total) were reduced at ≥ 1,000 mg/m^3. There was a significant increase in the incidence of a number of external, visceral and skeletal malformation, as well as skeletal variations, at ≥ 1,000 mg/m^3. There was no observable maternal or developmental toxicity at 150 mg/m^3. However, a NOAEC cannot be determined because of the amount of ethylene glycol that may have been ingested from the presence of ethylene glycol on the fur (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (nose-only) to 0, 500, 1,000 or 2,500 mg/m^3. The study also included a group exposed to 2,100 mg/m^3 (not discussed here). Reduced maternal body weight gain were seen in the 2,500 mg/m^3 for GD 9-12, 12-15, 6-15 and 0-18. Absolute kidney weights were increased in the ≥ 1,000 mg/m^3 groups. foetal body weights per litter were significantly reduced for the 2,500 mg/m^3. In the 2,500 mg/m^3, there was a significant increase in one skeletal malformation (fusion of the ribs) and an increased incidence of skeletal variations. No other teratogenic effects were observed. The NOECs for maternal and developmental toxicity are 500 and 1,000 mg/m^3, respectively (Tyl et al., 1995c) [Kl. score = 2].

Dermal

Pregnant CD-1 mice were administered by dermal applications of 0, 400, 1,677 or 3,549 mg/kg ethylene glycol 6 hours/day on GD 6-15. There was minimal, if any, treatment-related maternal toxicity. Copora lutea, total implants, percentage of live foetuses per litter, foetal body weights and incidence of external or visceral malformations were unaffected by treatment. There was, however,

a significant increase in two skeletal variations in the 3,549 mg/kg group. The NOAELs for maternal and developmental toxicity were considered to be 3,549 mg/kg/day (Tyl et al., 1995b) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The NOAEL from a 24-month rat dietary study was reported to be 200 mg/kg/day based on kidney lesions in male F344 rats at 1,000 mg/kg/day (DePass et al., 1986b). A subsequent 12-month rat dietary study using male Wistar rats reported a NOAEL of 150 mg/kg/day also based on kidney toxicity at 300 mg/kg/day and higher (Corley et al., 2008). The Wistar rat strain was shown to be more sensitive (approximately three-fold) to the kidney toxicity of ethylene glycol than F344 rats (Cruzan et al., 2004). The NOAEL of 150 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Snellings et al. (2013) derived an oral reference dose for ethylene glycol using benchmark dose modelling, with toxicokinetic (PBPK modelling) and toxicodynamic data. The human equivalent dose ($[BMDL_{05}]_{HED}$) was calculated to be 150 mg/kg/day.

Oral RfD = $[BMDL_{05}]_{HED}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 1
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 150/(1 x 10 x 1 x 1 x 1) = 150/10 = 15 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (15 x 70 x 0.1)/2 = 53 mg/L

B. Cancer

Ethylene glycol was not carcinogenic to rats and mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ethylene glycol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on ethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	>72,860	1	Pillard (1995)
Oncorhynchus mykiss	96-hour LC_{50}	22,810 24,591	2	OECD (2004a,b)
Daphnia magna	48-hour EC_{50}	>100	1	ECHA
Daphnia magna	48-hour EC_{50}	46,300	2	Gersich et al. (1986)
Ceriodaphnia dubia-affinis	48-hour EC_{50}	25,800 (20°C) 10,000 (24°C)	2	Cowgill et al. (1985)
Daphnia magna	48-hour EC_{50}	46,300 (20°C) 51,000 (24°C)	2	Cowgill et al. (1985)
Selenastrum capricornutum	96-hour IC_{50} NOEC	10,940 10,000	2	Pillard and DuFresne (1999)

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies conducted on ethylene glycol.

Table 4: Chronic Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	7-day NOEC	15,380	2	Pillard (1995)
Ceriodaphnia dubia	7-day NOEC (reproduction)	8,590	2	Pillard (1995)
Pseudokirchneriella subcapitata	72-hr NOEC	>100 *	2	ECHA

*Read-across to pentaethylene glycol (CAS No. 4792-15-8)

C. Terrestrial Toxicity

No guideline studies have been conducted on ethylene glycol.

D. Calculation of PNEC

The PNEC calculations for ethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (22,810 mg/L), *Daphnia* (>100 mg/L), and algae (10,940 mg/L). NOEC values from long-term studies are available for fish (15,380 mg/L), invertebrates (8,590 mg/L) and algae (10,000 mg/L). On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported E(L)C_{50} value of 100 mg/L for fish. The E(L)C_{50} value is used because the value for fish is lower than the NOEC values for all three trophic levels. The $PNEC_{aquatic}$ is 10 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.4 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.82/1280) \times 1000 \times 10$
$= 6.4$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.82\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.13 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 10

= 0.13 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ethylene glycol is readily biodegradable and thus does not meet the screening criteria for persistence.

The measured BCF in fish is 10. Thus, ethylene glycol does not meet the criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on ethylene glycol are > 0.1 mg/L. The acute $E(L)C_{50}$ values from the acute aquatic toxicity studies on ethylene glycol are > 1 mg/L. Thus, ethylene glycol does not meet the criteria for toxicity.

The overall conclusion is that ethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

STORE Category 2 (target organ: kidney)

B. Labelling

Warning

A. Pictogram



IX. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention.

Ingestion

Rinse mouth with water and then drink a glass of water. Get medical attention. Never give anything by mouth to an unconscious person.

Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

B. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Handle in accordance with good industrial hygiene and safety practice.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

For large amounts: dike spillage and pump off product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

C. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

D. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standards for ethylene glycol in Australia is as follows: 10 mg/m^3 as an 8-hour TWA for ethylene glycol (particulate); 20 ppm (52 mg/m^3) as an 8-hour TWA for ethylene glycol (vapour). There is also a skin notation indicating that absorption through the skin may be significant source of exposure.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

X. TRANSPORT INFORMATION

Ethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Blood, F.R. (1965). Chronic toxicity of ethylene glycol in the rat. Food Cosmet. Toxicol. 3: 229-234.

Carney, E.W., Pottenger, L.H., Bartels, M.J., Jaeckh, R., and Quast, J.F. (1998). Comparative pharmacokinetics and metabolism of ethylene glycol in pregnant rats and rabbits. Toxicol. Lett. 95: 208.

Chapin, R.E. and R.A. Sloane. (1997). Reproductive assessment by continuous breeding: evolving study design and summaries of ninety studies. Environ Health Perspect. 1997 Feb; 105(Suppl 1): 199–205.

Corley, R.A., Meek, M.E., and Carney, E.W. (2005a). Mode of action: oxalate crystal-induced renal tubule degeneration and glycolic acid-induced dysmorphogenesis – renal and developmental effects of ethylene glycol. Crit. Rev. Toxicol. 35: 691-702.

Corley, R.A., Bartels, M.J., Carney, E.W., Weitz, K.K., Soelberg, J.J., and Gies, R.A. (2005b). Development of a physiologically based pharmacokinetic model for ethylene glycol and its metabolite, glycolic acid, in rats and humans. Toxicol. Sci. 85: 476-490.

Corley, R.A., Wilson, D.M., Hard, G.C., Stebbins, K.E., Bartels, M.J., Soelberg, J.J., Dryzga, M.D., Gingell, K.E and Snellings, W.M.(2008). Dosimetry considerations in the enhanced sensitivity of male Wistar rats to chronic ethtlene glocol-induced nephrotoxicity. Toxicology and Applied Pharmacology. Volume 228, Issue 2: 165-178.

Cowgill, U.M., Takahash, I.T., and Applegath, S.L. (1985). A comparison of the effect of four benchmark chemicals on Daphnia magna and Ceriodaphnia dubia-affinis tested at two different temperatures. Environ. Toxicol. Chem. 4: 415-422.

Cruzan, G., Corley, R.A., Hard, G.C., Mertens, J.J., McMartin, K.E., Snellings, W.M., Gingell, R., and Deyo, J.A. (2004). Subchronic toxicity of ethylene glycol in Wistar and F-344 rats related to metabolism and clearance of metabolites. Toxicol Sci. 81: 502-11.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DePass, L.R., Garman, R.F., Woodside, M.D., Giddens, W.E., Maronpot, R.R., and Weil, C.S. (1986a). Chronic toxicity and oncogenicity studies of ethylene glycol in rats and mice. Fundam. Appl. Toxicol. 7: 547-565.

DePass, L.R., Woodside, M.D., Maronpot, R.R., and Weil, C.S. (1986b). Three-generation reproduction and dominant lethal mutagenesis studies with ethylene glycol in the rat. Fundam. Appl. Toxicol. 7: 566-572.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Evans, W.H., and David, E.J. (1974). Biodegradation of mono-, di-, and triethylene glycols in river waters under controlled laboratory conditions. Water Res. 8: 97-100.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996a). Pharmacokinetics of ethylene glycol. I. Plasma disposition after single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Drug Metab. Dispos. 24: 911-921.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996b). Pharmacokinetics of ethylene glycol. II. Tissue distribution, dose dependent elimination, and identification of urinary metabolites following single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Xenobiotica 26: 1195-1220.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. Chemosphere 14: 1589-1616.

Gersich, F.M., Blanchard, F.A., Applegath, S.L., and Park, C.N. (1986). The precision of Daphnid (Daphnia magna Straus, 1820) static acute toxicity tests. Arch. Environ. Contam. Toxicol. 15: 741-749.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Science 4: 67-80.

Hardin, B.D., Schuler, R.L., Burg, J.R., Booth, G.M., Hazelden, K.P., MacKenzie, K.M., Piccirillo, V., Jr, and Smith, K.N. (1987). Evaluation of 60 chemicals in a preliminary developmental toxicity test. Terat. Carcinogen. Mutagen. 7: 29-48.

Harris, M.W., Chapin, R.E., Lockhart, A.C., and Jokinen, M.P. (1992). Assessment of a short-term reproductive and developmental toxicity screen. Fundam. Appl. Toxicol. 19: 186-196.

Hess, R., Bartels, M.J., and Pottenger, L.H. (2004). Ethylene glycol: an estimate of tolerable levels of exposure based on a review of animal and human data. Arch. Toxicol. 78: 671-680.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Kurihara, A., Manabe, A., Katsuno, K., Itoh, K., Hisamitsu, H., Wakumoto, S., and Yoshida, T. (1996). Evaluation of skin irritation and sensitization of two diol solutions used as experimental dentin primers in humans and guinea pigs. Dent. Mater. J., 15: 226-232.

Lamb, J.C., IV, Maronpot, R.R., Gulati, D.K., Russel, V.S., Hommel-Barnes, L., and Sabharwa, l. P.S. (1985). Reproductive and developmental toxicity of ethylene glycol in the mouse. Toxicol. Appl. Pharmacol. 81: 100-112.

McGregor, D.B., Brown, A.G., Howgate, S., McBride, D., Riach, C., and Caspary, W.J. (1991). Responses of the L5178Y mouse lymphoma cell forward mutation assay. V: 27 coded chemicals. Environ. Mol. Mutagen. 17: 196-219.

Melnick, R.L. (1984). Toxicities of ethylene glycol and ethylene glycol monoether in Fischer 344/N rats and B6C3F1 mice. Environ. Health Perspect. 57: 147-155.

Neeper-Bradley, T.L., Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco P.E. (1995). Determination of a no-observed-effect level for developmental toxicity of ethylene glycol administered by gavage to CD rats and CD-1 mice. Fundam. Appl. Toxicol. 27: 121-130.

National Toxicology Program [NTP]. (1993). Toxicology and Carcinogenesis Studies of Ethylene Glycol in B6C3F1 Mice (Feed Studies). National Toxicology Program Technical Report Series No. 413.

OECD. (2004a). SIDS Dossier on the HPV Chemical Ethylene Glycol (CAS No. 107-21-1).

OECD. (2004b). SIDS Initial Assessment Report on the Ethylene Glycol Category: Ethylene Glycol (CAS No. 107-21-1), Diethylene Glycol (CAS No. 111-46-6), Triethylene Glycol (CAS No. 112-27-6), Tetraethylene Glycol (CAS No. 112-60-7), Pentaethylene glycol (CAS No. 4792-15-8).

Pillard, D. (1995). Comparative toxicity of formulated glycol deicers and pure ethylene and propylene glycol to Ceriodaphnia dubia and Pimephales promelas. Environ. Toxicol. Chem. 14: 311-315.

Pillard, D.A. and DuFresne, D.L. (1999). Toxicity of formulated glycol deicers and ethylene and propylene glycol to lactuca sative, lolium perenne, selenastrum capricornutum, and lemna minor. Arch Environ. Contam. Toxicol. 37(1):29-35.

Price, C.J., Kimmel, C.A., Tyl, R.W., and Marr, M.C. (1985). The developmental toxicity of ethylene glycol in rats and mice. Toxicol. Appl. Pharmacol. 81: 113-127.

Robinson, M., Pond, C.L., Laurie, R.D., Bercz, J.P., Henningsen, G., and Condie L.W. (1990). Subacute and subchronic toxicity of ethylene glycol administered in drinking water to Sprague-Dawley rats. Drug Chem. Toxicol .13: 43-70.

Schuler, R.L., Hardin, B.D., Niemeier, R.W., Booth, G., Hazelden, K., Piccirillo, V., and Smith, K. (1984). Results of testing 15 glycol ethers in a short-term in vivo reproductive toxicity assay. Environ. Health Perspect. 57: 141-146.

Snellings, W.M., Corley, R.A., McMartin, K.E., Kirman, C.R., and Bobst, S.M. (2013). Oral reference dose for ethylene glycol based on oxalate crystal-induced renal tubule degeneration as the critical effect. Regul. Toxicol. Pharmacol. 65: 229-241.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P. (2007). A review of large granular lymphocytic leukemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Fait, D.L., Savine, T.A., Dodd, D.E., Klonne, D.R., and Pritts, I.M. (1995a). Evaluation of the developmental toxicity of ethylene glycol aerosol in the CD rat and CD-1 mouse by whole-body exposure. Fundam. Appl. Toxicol. 24: 57-75.

Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco, P.E. (1995b). Assessment of the developmental toxicity of ethylene glycol applied cutaneously to CD-1 mice. Fundam. Appl. Toxicol. 27: 155-166.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Dodd, D.E., Klonne, D.R., Pritts, M., and Losco, P.E. (1995c). Evaluation of the developmental toxicity of ethylene glycol aerosol in CD-1 mice by nose-only exposure. Fundam. Appl. Toxicol. 27: 49-62.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Waggy, G.T., Conway, R.A., Hansen, J.L., and Blessing, R.I. (1994). Comparison of 20-d BOD and OECD closed-bottle biodegradation tests. Environ. Toxicol. Chem. 13: 1277-1280.

Fatty acids, tall-oil, ethoxylated

This dossier on Fatty acids, tall-oil, ethoxylated (FAT) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Fatty acids, tall-oil, ethoxylated

CAS RN: 61791-00-2

This CAS RN is broadly defined as "A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. Tall oil fatty acids (TOFA), generally any product containing 90% or more fatty acids and 10% or less of rosin, have grown in annual volume ever since, until they amount to 398.8 million pounds annual production in the U.S. in 1978. Crude tall oil is a byproduct of the Kraft process for producing wood pulp from pine wood. Crude tall oil is about 50% fatty acids and 40% rosin acids, the remainder unsaps and residues. Separative and upgrading technology involves: (a) recovery of the tall oil; (b) acid refining; (c) fractionation of tall oil; and occasionally (d) conversion to derivatives. TOFA of good quality and color of Gardner 2 corresponds to above 97% fatty acids with the composition of 1.6% palmitic & stearic acid, 49.3% oleic acid, 45.1% linoleic acid, 1.1% miscellaneous acids, 1.2% rosin acids, and 1.7% unsaponifiables.

Molecular formula: C(18-50)H(34-98)O(3-8) (UVCB substance)

Molecular weight: (UVCB substance)

Synonyms: IUPCA Name 2-[(10Z,13Z)-nonadeca-10,13-dienoyloxy]ethyl (10Z,13Z)-nonadeca-10,13-dienoate 2-hydroxyethyl (5Z,9Z,12Z)-octadeca-5,9,12-trienoate 2-hydroxyethyl (9Z)-octadec-9-enoate 2-hydroxyethyl (9Z,12Z)-octadeca-9,12-dienoate

SMILES: Not available (UVCB substance)

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Fatty acids, tall-oil, ethoxylated)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid.	2	ECHA
Melting point	-85 °C	2	ECHA
Boiling point	Not available. During the heating process the test item began to change its state at approximately 172 °C from liquid to highly viscous. This indicates a thermally caused change of the test item.	2	ECHA
Density	0.958 g/cm^3 @ 20°C	2	ECHA
Vapor pressure	The vapor pressure could not be determined.	2	ECHA
Partition coefficient (log K_{ow})	5.94	-	-
Water solubility	The test item can be mixed with water up to a ratio of 3:7 (m (test item) : :m (water)).	-	-
Flash point	Flash point at 101 325 Pa: 138 °C	2	ECHA
Auto flammability	377 °C at 1031 hPa	2	ECHA
Viscosity	58.0 mPa*s at 20 °C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

There are no biodegradation data on FAT. However, data on structurally similar substances suggest FAT is biodegradable with potential to sorb to soils. It is not expected to readily bioaccumulate.

B. Biodegradation

Data on the ready biodegradability of Fatty acids, tall oil, ethoxylated (EO > 1 < 2.5) (CAS 61791-00-2) are not available. Therefore, data on the ready biodegradability of the structurally related analogue substance Fatty acids, tall oil, ethoxylated (EO 5) (CAS No. 9004-96-0) is used as read-across in accordance with Regulation (EC) No. 1907/2006, Annex XI, 1.5.

This read-across is justified because both, target and source substance, are structurally identical (ethoxylated oleic acid) except for the fact that the source substance is slightly higher ethoxylated (5 EO) than the target substance (1-2.5EO). This difference might lead to a slightly lower water solubility of the target substance; however, since the solubility of both substances is rather high and not limiting the bioaccessibility of the substances to aquatic microorganisms this is not considered to influence the identical biodegradation behaviour of both substances. Both substances share the same functional groups and the same mode of action (baseline toxicity caused by the long lipophilic fatty acid chain). Thus, biotransformation can with very high certainty assumed to be identical.

The test with the source substance was conducted according to OECD Guideline 301B, under GLP conditions (BASF 2005). Domestic, non-adapted activated sludge was exposed to the test substance for 28 days at 22°C, and biodegradation was measured by CO2 consumption. After 28 days, the test substance reached a biodegradation of 90 - 100 %.

Based on the results for the read-across substance, Fatty acids, tall oil, ethoxylated (EO > 1 < 2.5) (CAS 61791-00-2) is considered to be readily biodegradable.

C. Environmental Distribution

One study investigating the adsorption/desorption behaviour of Fatty acids, tall-oil, ethoxylated (CAS 61791-00-2) is available. The study was performed according to GLP and OECD guideline 121 (BASF 2017). 6 different peaks were observed with log Koc values ranging from < 1.8 to > 5.63. The two main components (> 85%) show log Koc values > 4.

Thus, adsorption of Fatty acids, tall-oil, ethoxylated to solid soil is expected.

D. Bioaccumulation

The test substance consists of components with log Kow values in the range of 5 to > 10 (KOWWIN v1.68) indicating a potential for bioaccumulation. But due to rapid environmental biodegradation, metabolisation via enzymatic hydrolysis (monoesters and diesters) as well as sterical hindrance of crossing biological membranes (high molecular weight of diesters) a relevant uptake and bioaccumulation in aquatic organisms is not expected. This is supported by low BCF values of < 100 L/kg ww (BCFBAF v3.01, Arnot-Gobas, including biotransformation, upper trophic) calculated for different components of the UVCB (mono- and diester EO1 to EO5). Thus, taking all information into account, the test substance is not considered to be bioaccumulative.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The toxicity of fatty acids, tall-oil, ethoxylated is low by the oral and dermal routes. No data are available for evaluation of toxicity via the inhalation route. fatty acids, tall-oil, ethoxylated are not genotoxic; nor do they exhibit and evidence of reproductive or developmental toxicity in rats.

B. Acute Toxicity

In an acute oral toxicity study performed similar to OECD guideline 401 (BASF 1971), three groups of rats consisting of 10 animals/sex/dose were treated by single gavage application with an aqueous solution of the test substance (10000, 8000, 6400 mg/kg bw). The animals were observed for mortality and for clinical symptoms of toxicity over a period of 7 days. At the end of the observation period, the surviving animals were sacrificed for the purpose of necropsy. No mortality occurred at the tested concentrations. At all doses mastication, irregular breathing, redness of the eyes and closed eyes were seen immediately after dosing. The next morning mastication and irregular breathing was observed. On the following days, no clinical sings were observed. Pathological examination revealed hydrometra in 3 animals exposed to 10000 mg/kg bw, 2 animals exposed to 8000 mg/kg bw, and 3 animals exposed to 6400 mg/kg bw. Based on the results obtained under the test conditions of this study, the acute oral LD50 was determined to be > 10000 mg/kg bw.

In another acute oral toxicity study of similar design four groups of rats consisting of 5 animals/sex/dose were treated by single gavage application with an aqueous solution of the test substance (6400, 3200, 1600, 200 µL/kg). The animals were observed for mortality and for clinical symptoms of toxicity. At the end of the observation period, the surviving animals were sacrificed for the purpose of necropsy. No mortality occurred at the tested concentrations. At all doses on the day of the experiment, restless behaviour was observed after application. The animals had slightly accelerated breathing as well as ruffled fur. Four days after the application all animals were without clinical signs. In this study no pathological changes in the organs were observed. One animal showed bronchitis and bronchiectasis on both sides.

In an additional study a limit test was performed. 4 rats were treated by single administration with 2000 mg/kg of the test substance (2 animals/sex/dose). During the observation period of 14 days, no clinical symptoms of toxicity or mortality were observed.

The acute oral LD50 of the test substance was determined to be > 10000 mg/kg bw.

To evaluate the potential acute inhalation toxicity of the test substance an Inhalation Risk Test conducted according to a BASF internal testing method (BASF 1971). The test demonstrates the toxicity of an atmosphere saturated with vapours of the volatile components of a test substance at the temperature chosen for vapour generation (20 °C). Rats were exposed sequentially to the vapours, generated by bubbling 200 l/h air through a substance column of about 5 cm above a fritted glass disc in a glass cylinder. The animals were exposed for 8 hour. The exposure concentration was estimated to be 0.28 mg/L based on evaporated substance. In addition to mortality, clinical signs were recorded and necropsy on surviving animals performed. No mortality occurred and no clinical sign were noted during exposure and observation period. In one animal exposed for 8 hours hydrometra was observed after necropsy. Since no mortality occurred at the concentrations tested an LC50 estimation cannot be made.

In another Inhalation Risk Test of similar design, Rats (12 animals) were exposed sequentially to the vapours, generated by bubbling 200 l/h air through a substance column of about 5 cm above a fritted glass disc in a glass cylinder. This time vapours were generated at 20 °C as well as 50 °C. The exposure concentrations were 0.04 mg/L and 0.34 mg/L. Rats were exposed for 8 hour. As in the previous study, no mortality occurred after exposure up to 8 hours. Clinical sings observed in the animals exposed to the vapor generated at 20°C included mild escape attempts when exposure began and at the end of the exposure period slight eye irritation was observed. The next day, the animals were without symptoms. In the animals exposed to the vapor generated at 50 °C escape attempts were noted in the first 60 minutes of exposure. Exposure to the saturated atmosphere caused slight eye irritation. At the end of the exposure period, all clinical signs were resolved. Since no mortality occurred at the concentrations tested an LC50 estimation cannot be made.

Based on the inhalation studies, no conclusion on LC50 can be drawn, because the tested concentrations are too low in relation to the classification criteria.
There are no data to evaluate dermal toxicity of the substance to test animals.

C. Irritation

SKIN: Non-irritating

By using the currently available methods a single in vitro assay is not sufficient to cover the full range of skin irritating/corrosion potential. Therefore, two in vitro assays were part of an in vitro skin irritation and corrosion test strategy (BASF 2017): The Skin Corrosion Test (SCT) and Skin Irritation Test (SIT). However, the results derived with SIT (performed in a GLP-compliant study according to OECD 431, OECD 439, EU method B.40 BIS. And EU method B.46) alone were sufficient for a final assessment. Therefore, further testing in SCT was waived.

The potential of the test substance to cause dermal irritation was assessed by a single topical application of 30 µL of the undiluted test substance to a reconstructed three-dimensional human epidermis model (EpiDerm™). The irritation test was performed with three EpiDerm™ tissues which were incubated with the test substance for 1 hour followed by a 42-hour post-incubation period.

Tissue destruction was determined by measuring the metabolic activity of the tissue after exposure/post-incubation by using a colorimetric test. The reduction of mitochondrial dehydrogenase activity measured by reduced formazan production after incubation with a tetrazolium salt (MTT) was chosen as endpoint. The formazan production of the epidermal tissues treated with the test substance is compared to that of negative control tissues. The quotient of the values indicates the relative tissue viability.

The following results were obtained in the EpiDerm™ skin irritation test: 1) The test substance is able to directly reduce MTT. Therefore, an additional MTT reduction control KC (freeze-killed control tissues) was introduced. 2) The final mean viability of the tissues treated with the test substance determined after an exposure period of 1 hour with an about 42-hour post-incubation was 100.7%.

Based on the results observed and by applying the evaluation criteria, it was concluded that the test substance does not show a skin irritation potential in the EpiDerm™ in vitro skin irritation and corrosion test strategy under the test conditions chosen.
In a supporting skin irritation test two rabbits were treated for 1, 5, 15 min and 20 hours under occlusive conditions (BASF 1971). An application site of 2.5 x 2.5 cm was covered with the liquid test substance. After the application time (1, 5, 15 min and 20 h) the skin was washed with Lutrol (50%). The animals were observed for 8 days and skin changes were recorded daily. The report describes findings after 24 hours and at the end of the observation period (8 days). After 20 hours exposure to the test-substance one animals showed slight erythema after 24 hours (score 2). The observed redness was resolved by the end of the observation period, but a slight scaling was still present. The other animal exposed for 20 hours showed only some questionable erythema effect after 24 hours (score 1) which was fully reversible within 72 hours. No other effects were noted in the animals exposed for 20 hours. Of the animals exposed for shorter periods (1, 5, or 15 minutes) only one animal exposed for 15 minutes showed some questionable erythema which was fully reversible.

In another similar performed skin irritation test showed stronger effects (BASF 1966). The animals exposed for 20 hours showed strong to very strong erythema across the whole exposed area. After 8 days the redness in one animal was decreased to slight and had disappeared in the other. However, strong scaling was observed in both animals. In addition to the erythema a slight swelling was seen at 24 hours which also had disappeared after 8 days. The animals exposed for 15 minutes showed questionable erythema which was fully reversible. No ulcers, bleeding, or bloody scabs were observed. Animals exposed for shorter period did not show any signs of irritation. The OECD guideline 404 (Acute Dermal Irritation/Corrosion) states a typical exposure duration of 4 hour under open or semi-occlusive conditions. Therefore the test employing 20 hours exposure under occlusive conditions is considered a worst case situation,

Severe skin irritating effects were only seen in one of the study, however considering the worst case conditions these effects are questionable. In contrast, the in vitro guideline study the test substance was considered not to be skin irritant, which is supported by the other in vivo study.

Based on these data, the substance is not considered a skin irritant.

EYE: Non-irritating

The eye irritating potential of the test substance was tested in vitro (BASF 2017). By using the methods currently available a single in vitro assay is not sufficient to cover the full range of eye irritating potential. Therefore, two in vitro assays were part of this in vitro eye irritation test strategy: The Bovine Corneal Opacity and Permeability Test (BCOP Test) and EpiOcular Eye Irritation Test. However, in the current case the results derived with the EpiOcular test alone (which was applied conforming GLP and in accordance with OECD 492) were sufficient for a final assessment. Therefore, further testing in BCOP was waived.

The potential of the test substance to cause ocular irritation was assessed by a single topical application of 50 µL undiluted test substance to a reconstructed three-dimensional, human cornea model (EpiOcular™). Two EpiOcular™ tissues were incubated with the test substance for 30 minutes followed by a 2-hour post-incubation period. Tissue destruction was determined by measuring the metabolic activity of the tissue after exposure/post-incubation by using a

colorimetric test. The reduction of mitochondrial dehydrogenase activity measured by reduced formazan production after incubation with a tetrazolium salt (MTT) was chosen as endpoint. The formazan production of the epidermal tissues treated with the test substance is compared to that of negative control tissues. The ratio of the values indicates the relative tissue viability. The following results were obtained in the EpiOcular™ eye irritation assay: 1) The test substance is able to directly reduce MTT. Therefore, an additional MTT reduction control (freeze-killed control tissues (KC)) was introduced. 2) The final mean viability of the tissues treated with the test substance was 109.3%.

Based on the results observed in the EpiOcular Test alone and by applying the evaluation criteria, it was concluded that the test substance does not show an eye irritation potential in the in vitro eye irritation test strategy under the test conditions chosen.

In a supporting eye irritation test (BASF 1971) 50 µL of the test substance were applied to the conjunctival sac of one eye in 2 animals. The adjacent eye served as saline-control. The animals were observed after 1 and 24 h on the day of treatment and up to 8 days afterwards. The eyes were not washed out after 24 hours as specified in OECD Guideline 405. One hour after application of the test substance slight redness of the conjunctivae was observed in both animals. After 24 hours one animals still showed slight redness of the conjunctivae while the effects in the other animal were completely reversed. After 8 days both animals were without eye irritating effects.

In another supporting eye irritation test (BASF 1966) of the same design and exposure regime similar results were obtained. One hour after application of the test substance slight redness of the conjunctivae was observed in both animals. After 24 hours no eye irritation effect were observed until the end of the observation period.

Based on these results, the test substance is considered to be not irritating to the eyes.

D. Sensitization

The substance is considered to be a sensitizer based on results obtained via the Buehler test.

LLNA assay

The skin sensitising potential of the test substance was assessed using the radioactive Murine Local Lymph Node Assay in a GLP compliant study according to OECD no. 429, Commission Regulation (EC) No 440/2008 Part B, and EPA OPPTS 870.2600. The assay simulates the induction phase for skin sensitisation in mice. It determines the response of the auricular lymph nodes on repeated application of the test substance to the dorsal skin of the ears. Groups of 5 female CBA/J mice each were treated with 3%, 10% and 30% w/w preparations of the test substance in MEK (methyl ethyl ketone) or with the vehicle alone. The high concentration was selected based on the presence of ear irritation in a pretest using a 60% preparation. The study used 3 test groups and 1 control group. Each test animal was applied with 25 µL per ear of the respective test-substance preparation to the dorsum of both ears for three consecutive days. The control group was treated with 25 µL per ear of the vehicle alone. Three days after the last application the mice were injected intravenously with 20 µCi of 3H-thymidine in 250 µL of sterile saline into a tail vein. About 5 hours after the 3H-thymidine injection, the mice were sacrificed

and the auricular lymph nodes were removed. The weights of each animal's pooled lymph nodes were determined. Thereafter lymph nodes were pooled group wise and further evaluated by measuring their cellular content and 3H-thymidine incorporation into the lymph node cells (indicators of cell proliferation). Moreover, a defined area with a diameter of 0.8 cm was punched out of the apical part of each ear and for each test group the weight of the pooled punches was determined in order to obtain an indication of possible skin irritation. The stimulation indices (fold of change as compared to the vehicle control) for cell count, 3H-thymidine incorporation, lymph node weight and ear weight were determined. No signs of systemic toxicity were noticed. When applied as 3%, 10% and 30% preparations in MEK, the test substance did not induce a biologically relevant response (no increase to 1.5 fold or above of control value = stimulation index (SI) ≥ 1.5) in the auricular lymph node cell counts. There was no relevant increase in lymph node weights as well. Concomitantly, the increase of 3H-thymidine incorporation into the cells was not biologically relevant (no increase above the cut off stimulation index of 3) at this concentration. The 30% test-substance preparation caused a minimal increase in ear weights as indication of ear skin irritation. Thus, it is concluded that the test substance does not show a skin sensitising effect in the Murine Local Lymph Node Assay under the test conditions chosen.

Buehler test

The dermal sensitising potential of the test substance was investigated according to one of the methods recommended in the OECD Guideline No. 406, "Skin Sensitisation", 1992 and the EEC Guideline "EEC 92/69 part B6", 1992. The test used was the Buehler test.

The experiment was performed on 30 guinea pigs divided into a test group of 20 animals, and a control group of 10 animals. The study included an induction and a challenge phase. The animals in the test group were induced with the test article and the animals in the control group were induced with sterile distilled water. The induction procedure included a closed patch topical application for 6 hours once a week for 3 weeks.

The challenge procedure included a closed patch topical treatment of the test article on the flank 4 weeks after the first induction. All animals were challenged for 6 hours. The skin reactions were evaluated 24 and 48 hours after termination of the challenge application. The undiluted test article was used for the inductions as well as for the challenge application.

Slight erythema was observed in 8 and 6 animals after 24 and 48 hours, respectively. However, slight erythema was considered a marginal skin change due to other factors than skin sensitisation. After 24 hours a moderate erythema was seen in 1 animal and after 48 hours a moderate erythema was seen in 5 animals. Based on these results, the test substance is considered to be sensitising to the skin.

E. Repeated Dose Toxicity

Oral

An OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) was performed in 2015. The rat is the preferred animal species for reproduction studies according to the various test guidelines and the Wistar strain

was selected. This Wistar rat strain (Crl:WI(Han)) was selected since extensive historical control data were available for this strain.

Male and female rats were dosed with the substance by oral gavage with 0, 100, 300, 1000 mg/kg/day. No clinical effects were observed , no mortality was observed comma and body weight changes we're not significantly different from controls. There were no treatment related changes in food consumption during the entire study. Water consumption was not affected. There were no haematological effects nor effects on clinical biochemistry parameters. An assessment of functional observation battery indicated no effects no test substance related deviations relative to motor activity were noted. Organ Weights were not affected by exposure to the substance at any dose level. Gross pathological and histopathological findings did not indicate any adverse effects.

The NOAEL for general systemic toxicity was determined to be 1000 milligram per kilogram body weight per day.

Inhalation
No studies are available.

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

The test substance is not mutagenic in bacteria or mammalian cell lines. The key *in vitro* genotoxicity studies are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on C9-C14 Aliphatic Hydrocarbons (<2% Aromatics)

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Mammalian cell gene mutation (Chinese hamster V 79 cells)	-	-	1	ECHA
Chromosomal aberration (human lymphocytes)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies were available.

G. Carcinogenicity

No carcinogenicity studies are available on the substance.

H. Reproductive Toxicity

The substance - was tested in a combined repeated dose toxicity study with a reproductive/developmental toxicity screening test (OECD 422). Male and female Wistar rat strain (Crl:WI(Han)) rats were given oral gavage doses of 0, 100, 300, or 1,000 mg/kg-day. There was no indication of reproductive toxicity or any effects on tested endocrine system related parameters (T4 and TSH levels) at any dose level. The NOAEL for reproductive toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 1].

I. Developmental Toxicity

The substance was tested in a combined repeated dose toxicity study with a reproductive/developmental toxicity screening test (OECD 422). Male and female Wistar rat strain (Crl:WI(Han)) SD rats were given oral gavage doses of 0, 100, 300, or 1,000 mg/kg-day. There was no indication of teratogenic toxicity at any dose level. The NOAEL for developmental toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 1].

The NOAEL for reproductive toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for C12-C15 aliphatic hydrocarbons (<2% aromatics) follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Under the conditions of this Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, the oral administration by gavage of test substance to Wistar rats revealed no adverse signs of toxicity in male and female animals at a dose level of 1000 mg/kg bw/d. Thus, the no observed adverse effect level (NOAEL) for general systemic toxicity was 1000 mg/kg bw/d for male and female Wistar rats.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10

UF_H (intraspecies variability) = 10

UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 1,000/(10 x 10 x 1 x 3 x 1) = 1,000/300 = 3 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (3 x 70 x 0.1)/2 = 11 mg/L

B. Cancer

No carcinogenicity studies are available on C9-C14 aliphatic (<2% aromatic) hydrocarbon fluids. Thus, a cancer reference value was not derived for C12-C15 aliphatic hydrocarbons (<2% aromatics).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

The substance does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is of low acute toxicity concern to aquatic life.

B. Aquatic Toxicity

Acute Studies
There are no aquatic toxicity data on the substance are listed on Table 3.

Table 3: Acute Aquatic Toxicity Studies on Fatty acids, tall-oil, ethoxylated*

Test Substance	Test Species	Endpoint	Results (mg/L) [WAF]	Kl. score
Fatty acids, tall-oil, ethoxylated	*Danio rerio*	96-h LL_{50}	>100	1
Fatty acids, tall-oil, ethoxylated	*Daphnia magna*	48-h LL_{50}	12.41	1
Fatty acids, tall-oil, ethoxylated	*Pseudokirchnerella subcapitata*	72-h LL_{50}	39.7	1

*All studies used the water accommodated fractions (WAFs) of the test substance.

Chronic Studies
No chronic data were available

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for the substance follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results from acute toxicity studies are available for three trophic levels.

By applying an assessment factor of 100 to the daphnid E(L)C50 value of 12.41 the derived PNECaquatic for the substance of 0.12 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the PNECsed was calculated using the equilibrium partitioning method. The PNECsed is 6 mg/kg sediment wet weight.

The calculations are as follows:

PNECsed = (Ksed-water/BDsed) x 1000 x PNECwater
= (65/1280) x 1000 x 0.12
= 6 mg/kg

Where:
Ksed-water = suspended matter-water partition coefficient (m3/m3)

BDsed = bulk density of sediment (kg/m3) = 1,280 [default]

Ksed-water = 0.8 + [(0.2 x Kpsed)/1000 x BDsolid]
= 0.8 + [(0.2 x 133/1000 x 2400]
= 65

Where:
Kpsed = solid-water partition coefficient (L/kg).
BDsolid = bulk density of the solid phase (kg/m3) = 2,400 [default]

Kpsed = Koc x foc = 3321 x 0.04 = 133 L/kg

Where:
Koc = organic carbon normalized distribution coefficient (L/kg). The Koc for the substance acid calculated from EPISUITE™ using the Kow method is 3321 L/kg .
Foc = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The PNECsoil is mg/kg soil dry weight. The calculations are as follows:

PNECsoil = (Kpsoil/BDsoil) x 1000 x PNECwater
=
= 66/1500 x 0.12 = 5 mg/kg

Where:
Kpsoil = soil-water partition coefficient (m3/m3)
BDsoil = bulk density of soil (kg/m3) = 1,500 [default]

Where:
Kpsoil = Koc x foc = 3321 x 0.02 = 66 mg/kg

Koc = organic carbon normalised distribution coefficient (L/kg). The Koc for the substance calculated from EPISUITE™ using the Kow method is 3321 L/kg.
Foc = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

FAT was noted to be readily biodegradable. Thus, the substance is not expected to meet the screening criteria for persistence.

Modeling of a representative structure indicates FAT does not have the potential to bioaccumulate. Thus, FAT does not meet the screening criteria for bioaccumulation.

FAT did not exhibit substantial acute toxicity to fish, invertebrates, or algae. Thus, FAT is not expected to meet the screening criteria for toxicity.

The overall conclusion is that FAT is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Skin Irrit. 2

Eye Irrit. 2

Skin Sens. 1B

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If irritation occurs, get medical attention.

Skin Contact
Wash the contaminated area of with soap and water. Remove and isolate contaminated clothing. Launder contaminated clothing before reuse.

Inhalation
Move person to fresh air. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. Give artificial respiration if victim is not breathing.

Ingestion
Do not induce vomiting. Get medical attention immediately.

Notes to Physician
If ingested, material may be aspirated into the lungs and may cause chemical pneumonitis. Treat appropriately.

B. Fire Fighting Information

Extinguishing Media
Use water spray or fog, foam, dry chemical or carbon dioxide. Do not use straight streams of water.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapors, or spray Avoid contact with skin, eye, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Pick up with non-combustible absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Avoid breathing vapor or aerosol. Keep away from open flames, hot surfaces and sources of ignition. Provide sufficient ventilation in work area.

Storage
Keep container tightly closed and in a dry, well-ventilated place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for C12-C15 aliphatic hydrocarbons (<2% aromatics).

Engineering Controls
Use adequate ventilation to control air-borne concentrations.

Personal Protection Equipment
Respiratory Protection:
If workers are exposed to concentrations at a level that is not adequate to protect work health, they must use appropriate, certified respirators. The following type of respirator should be considered for this material: particulate, dust or mists. For high airborne concentrations, use an approved supplied-air respirator, operated in positive pressure mode.

Hand Protection:
Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection:
Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection:
Use chemical goggles.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

C12-C15 aliphatic hydrocarbons (<2% aromatics) is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

CONCAWE. PetroRisk: https://www.concawe.eu/reach/petrorisk/.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

FATTY ACIDS, C8-C16, 2-ETHYLHEXYL ESTERS

This dossier on fatty acids, C8-C16, 2-ethylhexyl esters presents the most critical studies pertinent to the risk assessment of fatty acids, C8-C16, 2-ethylhexyl esters in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Fatty acids, C8-C16 (even numbered), 2-ethylhexyl esters

CAS RN: 135800-37-2

Molecular formula: $C_{16}H_{32}O_2$ to $C_{24}H_{48}O_2$

Molecular weight: 256 to 352

SMILES:

Octanoic acid, 2-EH ester
O=C(OCC(CCCC)CC)CCCCCCC

Decanoic acid, 2-EH ester
O=C(OCC(CCCC)CC)CCCCCCCCC

Dodecanoic acid, 2-EH ester
O=C(OCC(CCCC)CC)CCCCCCCCCCC

Fatty acids, C8-C16, 2-ethylhexyl esters is an UVCB substance (substance of Unknown or Variable Composition, Complex Reaction Products or Biological Materials).

The main components of fatty acid, C8-C16, 2-ethylhexyl esters produced by BASF are 2-ethylhexyl laurate [C12] (CAS No. 20292-08-4) and 2-ethylhexyl octanoate [C8] (CAS No. 63321-70-0).

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Fatty Acids, C8-C16, 2-Ethylhexyl Esters

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, slightly yellow liquid	2	ECHA
Melting Point	-53 to -30°C	1	ECHA
Boiling Point	-	-	-
Density	870 kg/m^3 @ 20°C (calculated)	2	ECHA
Vapor Pressure	<0.029 Pa @ 20°C (calculated)	2	ECHA
Partition Coefficient (log K_{ow})	6.68 to 8.65* (calculated)	2	ECHA
Water Solubility	<0.05 mg/L @ 20°C (measured)	2	ECHA
Flash Point	186°C	1	ECHA
Auto flammability	235°C	2	ECHA
Viscosity	7.4 mPa s @ 20°C	2	ECHA

*Calculated from KOWWIN v 1.67 in EPISUITE™ v. 4.00 (EPA, 2017). Due to the fact that this substance is a long-chain hydrocarbon which exceeds the applicability domain of KOWWIN, the value for log K_{ow} is reported with restrictions. The applicability domain covers log K_{ow} up to 10 (maximum), so these values should be given as log K_{ow} >10. The concrete value is reported to show the high lipophilic nature of the substance.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Fatty acids, C8-C16, 2-ethylhexyl esters are readily biodegradable. They have a low potential to bioaccumulate. They are highly insoluble in water and have high adsorption potential; thus, sediment and soil are expected to be the main targets for environmental distribution.

B. Biodegradation

In an OECD 301 D test, 97% (2 mg/L) and >65% (5 mg/L) were degraded after 30 days, indicating that fatty acids, C8-C16, 2-ethylhexyl esters are readily biodegradable (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental studies are available on fatty acids, C8-C16, 2-ethylhexyl esters. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} values of the surrogate dodecanoic acid, 2-ethylhexyl ester from the molecular connectivity index (MCI) and from log K_{ow} are 79,726 and 200,032 L/kg, respectively (ECHA). [Kl. score = 2]

D. Bioaccumulation

No experimental studies are available on fatty acids, C8-C16, 2-ethylhexyl esters. Using BCFBAF in EPISUITE™, the estimated BCF of the surrogate dodecanoic acid, 2-ethylhexyl ester is 1,054 L/kg based on a regression based estimate and 39.76 L/kg based on the Arnot-Gobas model which includes biotransformation and upper trophic. There would be rapid metabolism of fatty acid esters (initial hydrolysis by carboxylesterases) and excretion of linear aliphatic fatty acid esters from fish. Thus, bioaccumulation is not expected (ECHA). [Kl. score = 2]

IV. HUMAN HEALTH HAZARD ASSESSMENT

Information can be found in the ECHA database under fatty acids, C8-C16, 2-ethylhexyl esters (CAS No. 135800-37-2), as well as under 2-ethylhexyl laurate (CAS No. 20292-08-4).

A. Summary

Fatty acids, C8-C16, 2-ethylhexyl ester has virtually no acute toxicity by the oral and dermal route. It is not irritating to the skin and eyes, and is not a skin sensitiser. No adverse effects were seen in animals given repeated doses by the oral route. Fatty acids, C8-C16, 2-ethylhexyl esters are not genotoxic when tested in both *in vitro* and *in vivo* assays. There is no indication that this substance will cause malformations or have an adverse effect on reproduction and development. Some of this information was derived from information in part from products of similar structures or composition.

B. Toxicokinetics/metabolism

Fatty acids, C8-C16, 2-ethylhexyl esters is expected to be hydrolyzed to 2-ethylhexanol and the corresponding saturated linear fatty acids in the body by serum carboxylesterases. The saturated linear fatty acids are metabolized via normal intermediary metabolism in the body. 2-Ethylhexanol is oxidized to 2-ethylhexanoic acid, which is further metabolized primarily by oxidation to dicarboxylic acid metabolites.

C. Acute Toxicity

The oral LD_{50} in rats of fatty acids, C8-C16, 2-ethylhexyl esters is >2,000 mg/kg (ECHA). [Kl. score = 2]. The oral LD_{50} in rats of 2-ethylhexyl laurate is >2,000 mg/kg (ECHA). [Kl. score = 2]

The inhalation 4-hour LC_{50} of 2-ethylhexyl oleate (as an aerosol) in rats is > 5.7 mg/L (ECHA). [Kl. score = 2]

No acute dermal studies are available.

D. Irritation

Application of 0.5 ml of fatty acids, C8-C16, 2-ethylhexyl esters to the skin of rabbits for 4 hours under occlusive conditions was slightly irritating; it was considered non-irritating according to GHS classification (ECHA). [Kl. score = 2]

Instillation of 0.5 ml of 2-ethylhexyl laurate into the eyes of rabbits was not irritating (ECHA). [Kl. score = 2]

E. Sensitization

Fatty acids, C8-C16, 2-ethylhexyl esters was not considered a skin sensitizer in a guinea pig maximization test (ECHA). [Kl. score = 2]

F. Repeated Dose Toxicity

Oral
Studies are not available for fatty acids, C8-C16, 2-ethylhexyl esters; however, a 28-day oral gavage study has been conducted on fatty acids, C8-C14, 2-ethylhexyl esters.

Male and female SD rats were dosed by oral gavage with 0, 100, 300, or 1,000 mg/kg fatty acids, C8-C14, 2-ethylhexyl esters 5 days/week for 28 days. There were no treatment-related effects on clinical signs, body weights, feed consumption, hematology and clinical chemistry parameters, neurotoxicity, necropsy observations, and histopathology. The NOAEL is 1,000 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 2]

Inhalation
No studies are available.

Dermal
No studies are available.

G. Genotoxicity

In Vitro Studies

Fatty acids, C8-C14, 2-ethylhexyl esters were not mutagenic to *S. typhimurium* strains TA98, TA100, TA1535, and TA1537 in the absence or presence of metabolic activation (ECHA) [Kl. score = 2].

2-Ethylhexyl oleate was not mutagenic in a mouse lymphoma assay with or without metabolic activation (ECHA) [Kl. score = 2].

There was no increase in chromosomal aberrations when peripheral human lymphocytes were treated with 2-ethylhexyl oleate with or without metabolic activation (ECHA) [Kl. score = 2].

In Vivo Studies

There were no increases in the incidence of micronucleated cells in the bone marrow of male and female CD-1 mice given a single intraperitoneal injection of 0, 1,075, 2,150, or 4,300 mg/kg fatty acids, C8-C16, 2-ethylhexyl esters (ECHA). [Kl. score = 2]

H. Carcinogenicity

No studies are available.

I. Reproductive Toxicity

Male and female SD rats were given in their diet ethyl oleate for 91 days. The estimated daily intakes are 0, 1,800, 3,600, and 5,500 mg/kg-day for males; and 0, 2,000, 3,900, and 6,100 mg/kg-day for females. There were no treatment-related effects on estrus cycles in females, sperm characterization in males, and histologic examination of male and female reproductive organs. The NOAEL for reproductive toxicity is 5,500 and 6,100 mg/kg-day for males and females, respectively (Bookstaff *et al.*, 2004; ECHA). [Kl. score = 2]

J. Developmental Toxicity

Female pregnant SD rats were dosed by oral gavage with 0, 100, 300, or 1,000 mg/kg 2-ethylhexyl stearate on gestational days 6 to 15. There was no maternal or developmental toxicity, with the NOAEL being 1,000 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for fatty acids, C8-C16, 2-ethylhexyl esters follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>
No repeated dose toxicity studies have been conducted on fatty acids, C8-C16, 2-ethylhexyl esters. However, a 28-day oral gavage study with rats was conducted on a similar material: fatty acid, C8-C14, 2-ethylhexyl esters. No effects were seen in this study and the NOAEL was 1,000 mg/kg-day, the highest dose tested (ECHA). The NOAEL from this study will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1

UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 1,000/(10 x 10 x 1 x 10 x 1) = 1,000/1,000 = 1.0 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (1.0 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

There are no carcinogenicity studies on fatty acids, C8-C16, 2-ethylhexyl esters. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Fatty acids, C8-C16, 2-ethylhexyl esters do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Fatty acids, C8-C16, 2-ethylhexyl esters are of low acute concern to aquatic organisms, at least in the range of its water solubility.

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies on fatty acid, C8-C16, 2-ethylhexyl esters.

Table 2: Acute Aquatic Toxicity Studies on Fatty Acids, C8-C16, 2-Ethylhexyl Esters

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Zebrafish	96-h LC_{50}	>10,000*	2	ECHA
Daphnia magna	48-h EC_{50}	>100** >100 (filtered test solution)[1]	1	ECHA
Daphnia magna	48-h EL_{50}	>100 (WAF)	1	ECHA
Scenedesmus subspicatus	72-h EC_{50}	<100 >100 (filtered test solution)[1]	2	ECHA

*There was increased turbidity of the test solutions with increasing concentrations; this indicates that effect concentrations exceeded the solubility of the test substance in the test medium.
**An average of 50% of the Daphnia were glued to oil drops at the surface or remained glued to the vessel walls.
[1]NOEC = 100 mg/L.

It should be noted that the water solubility of fatty acids, C8-C16, 2-ethylhexyl esters is <0.05 mg/L (ECHA).

Chronic Studies
A 21-day *Daphnia* reproduction test was conducted on fatty acids, C8-C16, 2-ethylhexyl esters. The test substance was stirred for 16 hours to 7 days; after a settling period of 2 hours, the solution was filtered through a glass fiber filter (activated with 1 mL NaOH and washed with deionized water). There was 10% mortality at 100 mg/L, but no mortality in control and at 1 mg/L. For reproduction, the EC_{50} and NOEC were >100 and >1 mg/L, respectively (ECHA) [Kl. score = 1].

C. Terrestrial Toxicity

The 14-day LC_{50} of isopropyl myristate (CAS No. 110-27-0), a surrogate for fatty acids, C8-C16, 2-ethylhexyl esters, to earthworms was >20,000 mg/kg soil dry weight (ECHA). [Kl. score = 2]

D. Calculation of PNEC

The PNEC calculations for fatty acids, C8-C16, 2-ethylhexyl esters follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. For the invertebrate and algal studies, there were no effects at the WAF loading rate or filtered test solution (100 mg/L

nominal). Long-term studies are also available for two trophic levels. For the chronic Daphnia study, the EC_{50} for reproduction is greater than the filtered tested solution at 100 mg/L (nominal), which is likely to be close to or at the water solubility limit. Assuming that the exposure concentration in the filtered test solutions (100 mg/L nominal) and WAF is the water solubility limit (saturation) for fatty acid, C8-C16, 2-ethylhexyl esters, the EC_{50} values and NOECs are >0.05 mg/L. On the basis that the data consists of short-term studies from three trophic levels and long-term studies from two trophic levels, an assessment factor of 50 has been applied to water solubility of fatty acids, C8-C16, 2-ethylhexyl esters of 0.05 mg/L. The $PNEC_{aquatic}$ is 0.001 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 1.2 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (1532/1280) \times 1000 \times 0.001$
$= 0.019$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 3189/1000 \times 2400]$
$= 1,532$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 79,726 \times 0.04$
$= 3,189$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for fatty acids, C8-C16, 2-ethylhexyl esters calculated from EPISUITE™ using the MCI is 79,726 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

Experimental results are available for one trophic level on a surrogate of fatty acids, C8-C16, 2-ethylhexyl esters. The acute LC_{50} value to earthworms is >20,000 mg/kg soil dry weight. On the basis that the data consist of one short-term result from one trophic level, an assessment factor

of 1,000 has been applied to the acute LC_{50} value of 20,000 mg/kg for earthworms. The $PNEC_{soil}$ is 20 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Fatty acids, C8-C16, 2-ethylhexyl esters are readily biodegradable; thus they do not meet the screening criteria for persistence.

Based on the estimated BCF values, fatty acids, C8-C16, 2-ethylhexyl esters do not meet the screening criteria for bioaccumulation.

The NOEC values from chronic aquatic toxicity studies on fatty acids, C8-C16, 2-ethylhexyl esters are greater than its water solubility. Thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that fatty acids, C8-C16, 2-ethylhexyl esters are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

No classification.

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention if symptoms persist.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam, carbon dioxide.

Specific Exposure Hazards
None known.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment.

Environmental Precautions
Not regarded as dangerous to the environment.

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for fatty acids, C8-C16, 2-ethylhexyl esters.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Minimize skin contact.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Minimize eye contact.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Fatty acids, C8-C16, 2-ethylhexyl esters is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BASF (2012). GPS Safety Summary: Fatty acids, C8-C16, 2-ethylhexyl ester. Available at: http://www.safety-summaries.basf.com/group/corporate/safety-summaries/en/literature-document:/GPS+Safety+Summaries--Fatty+acids+C8+16+2+ethylhexyl+ester-English.pdf.

Bookstaff, R.C., Stuard, S.B., Ward, S.R., Pesik, P.K., and Henwood, S.M. (2004). The safety of ethyl oleate is supported by a 91-day feeding study in rats. Regul. Toxicol. Pharmacol. 39: 202-213.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

GLUTARALDEHYDE

This dossier on glutaraldehyde presents the most critical studies pertinent to the risk assessment of glutaraldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from NICNAS (1994) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Glutaraldehyde

CAS RN: 111-30-8

Molecular formula: $C_7H_8O_2$

Molecular weight: 100.12 g/mol

Synonyms: Pentanedial; glutaral; glutaric dialdehyde; 1,3-diformylpropane; 1,5-pentanedial; glutaric aldehyde; glutaric acid dialdehyde; dioxopentane; glutardialdehyde; 1,5-pentanedione; Algicide®C

SMILES: C(CC=O)CC=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Glutaraldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	Sweetish smelling, clear water liquid	1	ECHA
Melting Point*	-33°C (pressure not provided)	1	ECHA
Boiling Point*	101.5°C @ 98.71 kPa	1	ECHA
Density*	1,130 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure*	21 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})*	-0.36 @ 23°C and pH 7	1	ECHA
Water Solubility*	Miscible @ 20°C	2	ECHA
Flash Point*	Not measurable	1	ECHA
Auto flammability*	395°C @ ~1,000hPa	1	ECHA
Viscosity*	12.75 mm^2/s (static) at 25°C	1	ECHA
Henry's Law Constant	0.011 Pa m^3/mol at 25°C [QSAR]	2	ECHA

*ca. 50% glutaraldehyde solution (in water)
1 ppm = 4.095 mg/m3
1 mg/m3 = 0.244 ppm

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Glutaraldehyde is considered readily biodegradable. It is also expected to have a low potential for bioaccumulation. The K_{oc} values for glutaraldehyde indicate that it will have low potential for adsorption to suspended solids and sediment in water and moderate adsorption to soil. Glutaraldehyde is not expected to undergo hydrolysis in the environment. Overall, glutaraldehyde shows limited persistence in the environment.

B. Partitioning

In an OECD TG 111 test (hydrolysis as a function of pH), glutaraldehyde was hydrolytically stable at pH 4 and pH 7 but decomposed at pH 9 (ECHA) [Kl. score = 2].

Photolytic degradation of glutaraldehyde occurred in water under sensitised conditions: the half-life was 18 days when equivalent to 36 days of natural sunlight (12 hours/day; sensitised acetone system); and 49 days when equivalent to 34 days of natural sunlight (12 hours/day; sensitised acetonitrile system). There was no photodegradation of glutaraldehyde under darkness or non-sensitised conditions (ECHA) [Kl. score = 2].

C. Biodegradation

Glutaraldehyde was considered readily biodegradable in an OECD 301A (DOC die away test). Degradation was 90-100% in 28 days (ECHA) [Kl. score = 1].

In a simulation test involving aerobic sewage treatment [activated sludge units] (OECD TG 303A), glutaraldehyde degraded 97% after 73 days based on DOC removal (ECHA) [Kl. score = 1].

In an aerobic aquatic metabolism test, [^{14}C]-glutaraldehyde had a half-life of 10.6 hours in the water/sediment system. A minor transformation product was glutaric acid: the maximum yield was 18.9 to 21.5% at 12 hours, which then declined rapidly to 10.1 to 11% by 24 hours; and was not observed at the end of the study period in the aqueous phase (ECHA) [Kl. score = 1].

In an anaerobic aquatic metabolism test, [^{14}C]-glutaraldehyde was rapidly metabolised with the first-order half-life being 7.7 hours. Glutaraldehyde was transformed to 5-hydroxypentanal (ca 37% of applied radioactivity) on day 1; after that, it declined to < 10%; it was not detected at all after 30 days. The second stable transformation product was 1,5-pentanediol (35% of radioactivity on Day 1), which accounted for 70% of the radioactivity at the end of the test. A minor transformation product was a compound formed via Aldol condensation, cyclisation and dehydration. This compound accounted for about 10-20% of total radioactivity from Day 1 onwards (ECHA) [Kl. score = 1].

In an aerobic soil metabolism test, the half-life of the degradation of [^{14}C]-glutaraldehyde was calculated to be 1.7 days, indicating rapid degradation in soil by microbial biotransformation. Degradation products were measured but not identified (ECHA) [Kl. score = 1].

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

The organic carbon/water partition coefficients (K_{oc}) values were determined for sediment and four types of soil. The values are as follows: 120 for sediment; 210 for sandy loam; 500 for silty clay loam; 340 for silt loam; and 460 for loamy sand (ECHA; Leung, 2001) [Kl. score = 1].

Based on these K_{oc} values, glutaraldehyde is considered to be moderately mobile in soil. If released to water, based on these K_{oc} values and its water solubility, it has moderate potential for adsorption to suspended solids or sediments.

E. Bioaccumulation

Glutaraldehyde is not expected to bioaccumulate. The measured log K_{ow} at pH 5, 7 and 9 are -0.41, -0.36 and -0.80, respectively (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has moderate-to-high acute toxicity by the oral route, low-to-moderate toxicity by the dermal route, and moderate-to-high toxicity by the inhalation route. Acute inhalation exposure may cause respiratory irritation. Glutaraldehyde is corrosive to the skin and eyes; it is also a skin and respiratory sensitiser. Repeated oral exposures via drinking water to rats have resulted in general systemic toxicity, but no target organ effects. In contrast, the upper respiratory tract, particularly the nasal cavity, is the target organ in rodents from repeated inhalation exposure. Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. Glutaraldehyde is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity.

B. Toxicokinetics

Dermal Absorption

[1,5-^{14}C]-glutaraldehyde was applied to the skin of male and female F344 rats. Doses were 0.75% and 7.5%: this corresponds to approximately 6.5 and 63 mg/kg for males; and approximately 8.7 and 102 mg/kg for females. The dermal absorption data are presented in Table 2. The results indicate that glutaraldehyde has a low rate of absorption by the dermal route (ECHA).

Table 2: Dermal Absorption Data in Rats on Glutaraldehyde (ECHA)

Sex	Absorption rate constant/hr		% of applied dose	
	Low Dose	High Dose	Low Dose	High Dose
Males	1.5	0.7	0.7	1.3
Females	1.8	0.9	0.3	2.1

An *in vitro* percutaneous absorption study was conducted on glutaraldehyde using excised skin from rats, rabbits, mice, guinea pigs and humans. The skin samples were placed in a flow-through skin penetration chamber, and [^{14}C]-glutaraldehyde was added at doses of 0.75% and 7.5%. The results are presented in Table 3. Glutaraldehyde did not penetrate any of the skin samples to a significant degree, suggesting that only minimal amounts of glutaraldehyde may be available for systemic

uptake and distribution after skin exposure. The results also show that skin absorption was greater for the animal species used in toxicity tests than human skin (ECHA; Frantz et al., 1993).

Table 3: *In vitro* Percutaneous Absorption (mg/cm^2) of Glutaraldehyde (ECHA; Frantz et al., 1993)

Species	Low Dose	High Dose
Animal*	0.006	0.08
Human	0.002	0.02

*Percutaneous absorption in rats, mice, guinea pigs, mice and rabbits were similar to each other and were reported as a single value.

C. Acute Toxicity

The oral LD_{50} values are: 123 to 820 mg/kg in rats; 100 to 352 mg/kg in mice; and 50 mg/kg in guinea pigs (NICNAS, 1994).

The dermal LD_{50} values are: 640 to 2,000 mg/kg in rabbits; > 2,500 mg/kg in rats; and > 4,500 mg/kg in mice (NICNAS, 1994).

The 4-hour inhalation LC_{50} values for glutaraldehyde are listed in Table 4:

Table 4: Acute inhalation LC_{50} values for Glutaraldehyde

Test Material	LC_{50} (males) [mg/L]	LC_{50} (females) [mg/L]	LC_{50} (both sexes) [mg/L]	Reference
50% aq. aerosol	0.52	0.45	-	OECD, 1995
25% aq. aerosol	-	-	0.8	OECD, 1995
50% aq. aerosol	0.35	0.28	-	OECD, 1995
5% soln. vapour	0.096	0.164	-	OECD, 1995

During the exposure period, the animals showed signs of eye and respiratory irritation, as indicated by laboured and audible breathing, and wetness and encrustation around the nose and eyes.

D. Irritation

Glutaraldehyde is corrosive to the skin and eyes of rabbits (NICNAS, 1994; ECHA). Signs of irritation occurred at a concentration of 2% for skin and 0.2% for eyes (NICNAS, 1994). In the acute inhalation studies, rats exposed to aerosols or vapours of glutaraldehyde showed signs of eye and respiratory irritation (OECD, 1995).

E. Sensitisation

Glutaraldehyde is a skin sensitiser to guinea pigs and humans. Information on the individual studies can be found in NICNAS (1994) and in the ECHA REACH database (ECHA).

Asthmatic symptoms, such as wheezing, coughing, chest tightness, breathing difficulties and non-specific hyper-responsiveness have been reported to occur in humans occupationally exposed to glutaraldehyde (NICNAS, 1994). It is unclear whether the asthma is an allergic hypersensitivity response or a result of the aggravation of pre-existing asthma due to the irritating properties of

glutaraldehyde. Nevertheless, glutaraldehyde should be considered a respiratory sensitiser, although one of low potency.

F. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their drinking water 0, 100, 500, or 2,000 ppm glutaraldehyde for 90 days. The approximate daily intakes were 0, 3, 15 or 53 mg/kg/day for males, and 0, 4, 19 or 72 mg/kg/day for females. There were no signs of neurotoxicity at any dose level. There was slight impairment of food consumption in the 2,000 ppm animals, as well as slight impairment of body weight and body weight gain. Impaired water consumption was seen in the 100 and 500 ppm females. The NOAEL for males is 500 ppm (15 mg/kg/day). The NOAEL for females is 100 ppm (4 mg/kg/day) since the impaired water consumption in the 100 ppm females was considered a palatability problem and not an adverse effect (ECHA) [Kl. score = 1].

Male and female F344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 13 weeks. Additional groups of animals were given in their drinking water 0 or 1,000 ppm glutaraldehyde for 13 weeks followed by a 4-week recovery period. The approximate daily intakes were 0, 5, 25 or 100 mg/kg/day for males; and 0, 7, 35 or 120 mg/kg/day for females. Water consumption was reduced in a dose-dependent manner in the $\geq$ 250 ppm males and 1,000 ppm females, which was attributed to an aversion to the taste and/or odour of glutaraldehyde in the water. There was also a reduction in food consumption in the 1,000 ppm animals with a parallel reduction in body weights. It is unclear whether the reduction in food consumption was related to the decreased water consumption. Urine volume was decreased with an increase in specific gravity, along with a slight increase in protein and ketone concentration, in the $\geq$ 250 ppm animals, which was probably related to the decreased water consumption. There were no treatment-related changes in the haematology parameters measured. Blood urea nitrogen was increased in a dose-related manner in the $\geq$ 250 ppm females at the 6-week time point, but not at the 13-week or 17-week time points. Relative kidney weights were increased in a dose-related manner in the $\geq$ 250 ppm males and females and increased absolute kidney weights in the females. Histopathological examination showed no treatment-related effects. The NOAEL is 50 ppm (5 and 7 mg/kg/day for males and females, respectively) based on dose-related increase in kidney weights at $\geq$ 250 ppm (ECHA) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for 12 months. The approximate daily intakes were: 0, 6.4, 30.5, or 116.6 mg/kg/day for males; and 0. 9.6, 46, or 153 mg/kg/day for females. There was no treatment-related mortality. At 2,000 ppm, treatment-related effects included respiratory sounds (both sexes), decrease in body weight (males), decrease in body weight gain (both sexes), decrease in food consumption (both sexes), reduced water consumption (both sexes), lesions within the glandular stomach (both sexes showed erosion/ulceration of the glandular stomach), increased incidence of clear cell foci in the liver (males) and a single case of slight diffuse squamous metaplasia in the epithelium of the larynx (male). At 500 ppm, water consumption was reduced in males which was considered to be a palatability (bad taste) problem and not an adverse effect. No effects were seen in the 100 ppm animals. The NOAEL for this study is 500 ppm, which corresponds to 30.5 and 46 mg/kg/day for males and females, respectively (ECHA) [Kl. score = 1].

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. There were no treatment-related mortalities or clinical symptoms of toxicity. In the 250 and 1,000 ppm groups, there was reduction in

body weight and body weight gain; reduction in food and water consumption; increased statistically significant incidence of nucleated erythrocytes and of large monocytes; decreases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and glutamate dehydrogenase; dose-related decrease in urine volume accompanied by a dose-related increase in osmolality; changes in absolute and relative kidney weight; gastric irritation; increases in bone marrow hyperplasia; and increased incidence of renal tubular pigmentation. The decreased water consumption was considered to be due to the bad taste, smell and/or irritancy of the test substance in the drinking water; thus, it is of no toxicological relevance. As a result of reduced water intake, there are renal physiological adaptation, such as decreased urine, increased osmolality and changes in kidney weight. The haematological and clinical chemistry parameter changes were marginal and were considered to be of no toxicological relevance. The main haematological finding seen at the end of the study, which consisted of the appearance of nucleated erythrocytes and large monocytes in all treated groups (statistically significant for the ≥250 ppm males), was related to the incidence of large granular lymphocytic leukaemia (LGLL) in the spleen. The bone marrow hyperplasia and renal tubular pigmentation are related to the occurrence/incidence of LGLL and were considered by the authors of the study as being secondary to low-grade haemolytic anaemia in animals with LGLL. The NOAEL for this study is 50 ppm which corresponds to 4 and 6 mg/kg/day for males and females, respectively (Van Miller et al., 2002) [Kl. score = 2].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathological lesions in the nasal passages and turbinates were seen at ≥ 0.25 ppm. Treatment-related effects were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing concentration of glutaraldehyde. The NOAEL for this study is 0.125 ppm (Gross et al., 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathologic lesions in the nasal passages and turbinates were seen at all exposure concentrations (≥ 0.0625 ppm). Treatment-related lesions were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing test concentration. Furthermore, neutrophilic inflammation was seen at ≥ 0.062 ppm, and squamous metaplasia as well as necrosis were seen in the larynx at 1 ppm. The LOAEL for this study is 0.0625 ppm; a NOAEL was not established (Gross et al*.,* 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.41 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. Survival was similar between treated and control groups. Hyperplasia of the squamous epithelium lining of the dorsal wall of the nasal passages and the lateral aspect of the atrioturbinate was seen in a greater number of exposed females than in controls. Epidermal erosion and ulceration as well as squamous and inflammatory exfoliation were also seen in the nasal lumens. All of these changes were dependent on the length of

glutaraldehyde exposure. The authors concluded that, since the induced lesions occurred in the more anterior part of the nasal passages, that they were likely the result of an irritation mechanism (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5, or 0.75 ppm (0, 1, 2, or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Mean body weights of all exposed males and the mid- and high-dose females were generally less than those of the controls. Non-neoplastic lesions were limited primarily to the most anterior region of the nasal cavity. Effects included hyperplasia and inflammation of the squamous epithelium; hyperplasia, goblet cell hyperplasia, inflammation and squamous metaplasia of the respiratory epithelium; and hyaline degeneration of the olfactory epithelium. The LOAEL for this study is 0.25 ppm based on hyperplasia and inflammation of the squamous epithelium of the nose in both sexes. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. Mean body weights of the high-dose females were generally lower than the controls. Non-neoplastic lesions were limited primarily to the anterior region of the nasal cavity; the effects were qualitatively similar to those seen in the rats (see accompanying summary on the two-year rat study by van Birgelen et al. [2000]). Squamous metaplasia of the respiratory epithelium was observed in both sexes of mice while female mice also had inflammation and hyaline degeneration of the respiratory epithelium. The incidence and severity grade (in parentheses) of the hyaline degeneration were: 16/50 (1.4), 35/49 (1.4), 32/50 (1.3) and 30/50 (1.1) for the 0, 0.0625, 0.125 and 0.25 ppm dose groups, respectively. The LOAEL for this study is 0.0625 ppm based on hyaline degeneration of the respiratory epithelium in female mice. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Dermal

Applications of a 50% solution of glutaraldehyde was applied to the skin of male and female SD rats for 13 weeks. The doses were 0, 50, 100 and 150 mg/kg glutaraldehyde. At the application site, there were signs of irritation (scabs, desquamation and very slight or well-defined erythema). There was no treatment-related mortality, clinical signs, body weights, feed consumption and ophthalmoscopic effects. There were no changes in the haematology and clinical chemistry parameters that were considered to be biologically or toxicologically relevant. Organ weights were similar between treated and control animals. Histopathological examination showed treatment-related effects in the skin associated with chronic irritation; no other changes were noted that were considered to be treatment-related. The NOAEL for this study is 150 mg/kg, the highest dose tested (ECHA) [Kl. score = 1].

G. Genotoxicity

In Vitro Studies

Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests. The bacterial reverse mutation assays have been the most consistent. Variable results have been reported for the forward gene mutation tests; and for sister chromatid exchange (SCE), chromosomal aberration and Unscheduled DNA Synthesis (UDS) tests (Vergnes and Ballantyne, 2002).

In Vivo Studies

The *in vivo* studies conducted on glutaraldehyde are presented in Table 5. All the studies show that glutaraldehyde is not mutagenic or genotoxic.

Table 5: *In Vivo* Genotoxicity Studies on Glutaraldehyde

Test System	Results*	Klimisch Score	Reference
Rat bone marrow (chromosomal aberration)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Mouse bone marrow (micronucleus)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Drosophila SLRL Test	-	2	ECHA
Rat liver UDS Assay	-	1	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Mouse peripheral blood micronucleus study	-	2	Vernes and Ballantyne (2002)
Rat liver UDS Assay	-	2	Mirsalis *et al.* (1989)

* +, positive; -, negative

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. Mortality rates were 25-30% and 19-23% for males and females, respectively, with no dose-related increase. The major cause of death in all dose groups including the controls was LGLL. There was an increased incidence of LGLL in the liver and spleen in all treated females ($\geq$ 50 ppm). The incidence of LGLL was not significantly increased in the treated males compared to the controls. No other treatment-related increased incidence of tumours was seen (Van Miller et al., 2002) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for two years. The mean daily intake of glutaraldehyde was as follows: 0, 6.1, 31.9 and 120.7 mg/kg/day for males; and 0, 10.5, 48.5 and 176.4 mg/kg/day for females. In the high-dose animals, there was mortality (2 males and 9 females) from asphyxia, and mean terminal body weights were significantly decreased compared to the controls. There were no treatment-related neoplastic effects (ECHA) [Kl. score = 1].

Inhalation

Male and female $B6C3F_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.4 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. No exposure-related neoplastic lesions were observed in either males or females (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5 or 0.75 ppm (0, 1, 2 or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Survival of the treated males was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

I. Reproductive Toxicity

A two-generation reproductive toxicity study was conducted in Wistar rats given 0, 100, 500 and 2,000 ppm glutaraldehyde in their drinking water. The approximately mean daily intake is 0, 12, 58 and 199 mg/kg/day for the parental males and females of the F_0 and F_1 generation during premating. There were no adverse effects on reproductive performance or fertility. Oestrous cycle data, mating behaviour, conception, gestation, parturition, lactation and weaning as well as sperm parameters, sexual organ weights, gross and histopathological findings of these organs were similar between treated and control groups. In the high-dose animals, there was decreased water and/or food consumption; and decreased body weights and/or reduced body weight gains during the premating periods in the F_0 and F_1 parental females during premating, gestation and/or lactation. The high-dose F_1 parental females also had increased the number of erosions/ulcers with microscopic erosion(s) or inflammatory oedema in the mucosa/submucosa of the glandular stomach. There were no adverse effects in the 500 ppm animals except for slight decreases in water consumption due to a palatability (bad taste) problem. Treatment-related signs of developmental toxicity were seen in the progeny of the high-dose F_0 and F_1 parental generation and included impairment in body weight and consequently in organ weights in the respective F_1 and F_2 pups. The NOAEL for reproductive toxicity is 2,000 ppm (199 mg/kg/day), the highest dose tested. The NOAEL for parental systemic toxicity is 500 ppm (58 mg/kg/day). The NOAEL for developmental toxicity is 500 ppm or 58 mg/kg/day (ECHA) [Kl. score = 1].

A two-generation reproductive toxicity study was conducted in Crj: CD(SD) rats given 0, 50, 250 and 1,000 ppm glutaraldehyde in their drinking water. Mean daily intake was not calculated. Parental body weights and body weight gains were significantly reduced at 1,000 ppm at some periods, particularly during pre-mating. Food consumption was significantly reduced at 1,000 ppm for the F_0 and F_1 parental animals during pre-mating and gestation, and F_1 females during lactation. Water consumption was reduced throughout the pre-mating period for the F_0 and F_1 250 and 1,000 ppm parental animals. There was no indication of adverse effects on reproductive performance or fertility at any dose level. For the F_1 1,000 ppm offspring, body weights were reduced from lactation days 21-28. The NOAEL for reproductive toxicity is 1,000 ppm, the highest dose tested. The NOAEL for parental systemic toxicity is 50 ppm. The NOAEL for developmental toxicity is 250 ppm (Neeper-Bradley and Ballantyne, 2000) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Wistar rats were given in their drinking water 0, 50, 250 or 750 ppm (0, 5, 26 or 68 mg/kg) glutaraldehyde from GD 6 to 16. Water consumption was reduced in a dose-related manner in the $\geq$ 250 ppm dams, and was considered not to be a toxic response, but due to the palatability (bad taste) of the drinking test solution. No other maternal effects were seen in the study. There were no significant differences between treated and controls in the sex distribution, placental weights, foetal

weights, malformations or variations. The NOAEL for maternal and developmental toxicity in this study is 68 mg/kg/day, respectively (ECHA) [Kl. score = 1].

Pregnant Wistar rats were dosed by oral gavage with 0, 25, 50 or 100 mg/kg glutaraldehyde on GD 6 to 15. Mortality was significantly increased in the high-dose group (5/26); there were 2/21 deaths in the mid-dose group. Clinical signs (piloerection) occurred in all treated groups in a dose-dependent manner. Maternal body weight gain and feed consumption were significantly reduced in the high-dose dams, but not at the lower doses. The necropsy findings showed evidence of stomach irritation in almost all of the animals that died during the study and in 12/21 of the surviving dams in the high-dose group. The number of implantations per litter, resorptions and dead foetuses per litter, live foetuses per litter and incidence of post-implantation loss per litter was similar across all groups. The mean foetal body weights for male and female foetuses were significantly reduced in the high-dose group; this was attributed to the reduced food consumption of the dams during gestation rather than a direct effect of treatment. There was no evidence of a treatment-related teratogenic effect. The NOAEL for maternal and developmental toxicity is 50 mg/kg/day, respectively (Ema et al., 1992) [Kl. score = 2].

Pregnant Himalayan rabbits were dosed by oral gavage with 0, 5, 15 or 45 mg/kg glutaraldehyde on GD 7 to 19. In the high-dose group, 5/15 died on GD 9-11. Food consumption and body weight gain were also significantly reduced in the high-dose group. Clinical observations in 12/15 high-dose does included soft faces, diarrhoea and blood in the bedding. The mean gravid uterus weight was significantly reduced in the high-dose group. Post-implantation loss was greatly increased (94.3%) in the high-dose group: no viable foetuses in 9/15 of the high-dose does, only early resorptions; only one female gave four alive foetuses on the scheduled date. There were reduced placental and foetal body weights in the only four foetuses. No significant maternal or developmental effects were seen in the mid- and low-dose groups. The NOAEL for maternal and developmental toxicity in this study is 15 mg/kg/day (ECHA) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for glutaraldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

The lowest NOAEL values from key toxicity studies on glutaraldehyde are listed in Table 6.

Table 6: Lowest NOAEL Values from Key Toxicity Studies on Glutaraldehyde by the Oral Route

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, female	90/days	4	Decreased body weights, food and water consumption	ECHA
Rats, male	13-wk (drinking water)	5	Increased kidney weights	ECHA

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, male	12-months (drinking water)	30.5	Clinical signs; decreased body weights and food consumption; increased clear cell foci in liver	ECHA
Rats, male	2-yr (drinking water)	4	Reduced body weight, body-weight gain, and food consumption	Van Miller *et al.* (2002)
Rats	2-generation (drinking water)	58	Systemic toxicity	ECHA
Rats	GD 6-16 (drinking water)	68	Developmental toxicity	ECHA
Rats	GD 6-15 (oral gavage)	50	Developmental toxicity	Ema *et al.* (1992)
Rabbits	GD 7-19 (oral gavage)	15	Developmental toxicity	ECHA

The lowest NOAEL from these studies is 4 mg/kg/day based on reduced body weights, body weight gain and feed consumption in male rats from the two-year drinking water study (Van Miller et al., 2002). The NOAEL of 4 mg/kg/day will be used for determining the oral Reference Dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4/(10 x 10 x 1 x 1 x 1) = 4/100 = <u>0.04 mg/kg/day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD: Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2 L (ADWG, 2011)
Drinking water guidance value = (0.04 x 70 x 0.1)/2 = 0.14 mg/L

B. Cancer

Increased incidence of large granular cell lymphatic leukaemia (LGLL) was observed in all groups of male and female Fischer 344 rats given glutaraldehyde in their drinking water, including the controls (Van Miller *et al.,* 2002). For the males, the incidence of LGLL was not statistically significantly increased. However, for the females, the incidence of LGLL was significantly increased in all treated females (≥ 50 ppm). Inhalation exposure of Fischer 344 rats to glutaraldehyde did not result in an increased incidence of tumours, including LGLL.

LGLL, also known as mononuclear cell leukaemia, is an extremely common spontaneous neoplastic disease of the ageing F344 rat (Stromberg, 1985; Ward *et al.* 1990; Thomas et al., 2007). Consistent features are splenomegaly, anaemia, thrombocytopenia and leukemic infiltration of the spleen, liver, lung, and in an advanced stage, of several other organs. The incidence is variable but has been increasing progressively with time and can exceed 70% in controls in some studies. This compares with background incidence of less than 1% in other strains of commonly used laboratory rats (Haseman et al., 1998; Thomas et al., 2007). The incidence in F344 rats is modulated by a variety of factors not clearly related to carcinogenicity. Corn oil gavage, for example, has been shown consistently to reduce the incidence of MCL in male, but not female, controls (reviewed in Thomas et al., 2007).

The neoplastic mononuclear cells appear to be derived from large granular lymphocytes (LULs) (reviewed in Thomas et al., 2007). The tumour cell is of the NK type in most, if not all, cases. LGL leukaemia, although uncommon, does occur in humans. There are two types: T-LGL leukaemia which has a chronic course characterised by neutropenia, recurrent infections, splenomegaly and accompanying rheumatoid arthritis, and the much rarer NK-LGL leukaemia which has an acute course, more pronounced splenomegaly, and thrombocytopenia. The latter type appears to resemble more closely the disease in the F344 rat than the former. The aetiology of human LGL leukaemia is unknown. There is some evidence that viral infection may play a role but no evidence that a chemically-related increased of LGLL in the F344 rat is indicative of the potential to induce LGL leukaemia in humans.

To extrapolate results from an animal model that has a clear predisposition (high spontaneous rates) to a tumour type to humans, of which this is not the case, seems inappropriate if the mechanism(s) for LGLL formation in that strain is not understood. Although that rat strain may be useful for understanding the disease process in humans, it does not seem reasonable to use the results from that rat strain for risk assessment purposes. There should be confirmation of a putative leukemogenic effect in the F344 rat in another strain before any conclusions are made about the use of this tumour type for human health risk assessment purposes.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Glutaraldehyde does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has a moderate acute toxicity concern to fish and invertebrates, but is highly toxic to algae. It is of low toxicity concern to terrestrial invertebrates and plants. To birds, glutaraldehyde is moderately toxic on an acute basis and slightly toxic on a subacute dietary basis.

B. Aquatic Toxicity

Acute Studies

Table 7 lists the results of acute aquatic toxicity studies conducted on glutaraldehyde.

Table 7: Acute Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill sunfish	96-hr LC_{50}	13	2	ECHA
Oncorhynchus mykiss	96-hr LC_{50}	10	2	ECHA
Daphnia magna	48-hr LC_{50}	14.87	2	ECHA
Daphnia magna	48-hr LC_{50}	14	2	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.375 (biomass) 0.6 (growth rate) 0.025 (NOEC)	1	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.92 (growth rate) 0.61(biomass) 0.33 (NOEC)	2	ECHA; Leung, 2001
Scenedesmus subspicatus	72-hr EC_{50}	0.61 (growth rate)	2	ECHA

Chronic Studies

The chronic aquatic toxicity studies conducted on glutaraldehyde are listed in Table 8.

Table 8: Chronic Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Kl. score	Reference
Oncorhynchus mykiss	97/day (OECD 210)	LOEC = 5 NOEC = 1.6	1	ECHA
Daphnia magna	21/day	NOEC = 5	1	ECHA

C. Terrestrial Toxicity

Table 9 lists the results of toxicity studies conducted on glutaraldehyde with earthworms, soil microorganisms and birds.

Table 9: Terrestrial Toxicity Studies on Glutaraldehyde

Test Species (method)	Endpoint	Results	Kl. score	Reference
Earthworm *Eisenia fetida* (OECD 207)	14-d LC_{50}	> 500 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 216)	28-d EC_{50} 28-d EC_{10}	360 mg/kg soil dw 11.5 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 217)	28-d EC_{50} 28-d EC_{10}	> 593 mg/kg soil dw 1.5 mg/kg soil dw	1	ECHA
Mallard ducks	Single-dose (oral gavage) LC_{50}	206 mg/kg	2	ECHA
Mallard ducks	5-d (dietary) NOEC	> 2,500 ppm	1	ECHA

*organic carbon content of soil = 1.34% dry weight

Glutaraldehyde has also been evaluated in a terrestrial plants test: seedling emergence and seedling growth test (OECD TG 208). The test material contained 48.9% glutaraldehyde. The results are as follows:

Avena sativa (oats): 19/day EC_{50} value is > 1,000 mg/kg soil dry weight based on emergence rate, dry weight and shoot length. The NOECs for *Avena sativa* (oats) were $\geq$ 1,000 mg/kg dry weight on all three parameters tested.

Brassica napus (rapeseed): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length and 994 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 500 and 250 mg/kg soil dry weight for emergence rate, dry matter and shoot length, respectively.

Vicia sativa (vetch): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length, and 901 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 125 and 125 mg/kg soil dry weight for emergence rate, dry matter, and shoot length, respectively (ECHA) [Kl. score = 1].

D. Calculation of PNEC

The PNEC calculations for glutaraldehyde follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (10 mg/L), *Daphnia* (14 mg/L) and algae (0.375 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 0.025 mg/L for algae. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 0.025 mg/L for algae. The $PNEC_{water}$ is 0.0025 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.006 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (3.1/1280) \times 1000 \times 0.0025$
$= 0.006$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 4.8)/1000 \times 2400]$
$= 3.1\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{0c} \times f_{oc}$
$= 120 \times 0.04$
$= 4.8$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for glutaraldehyde in sediment is 120.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil

Experimental results are available for three trophic level. An acute LC_{50} value is available for earthworms (> 500 mg/kg). Results from long-term studies are available for two trophic levels, with the lowest NOEC or EC_{10} being 1.5 mg/kg soil dry weight for soil organisms.

The EC_{10} value is corrected for bioavailability of glutaraldehyde in soil by normalising to the fraction organic carbon matter content (Fom) in the soil using the following equation:

$EC_{10(std)} = EC_{10(exp)} \times Fom_{soil(std)}/Fom_{soil(exp)}$

Where:
$Fom_{soil(std)}$ = 1% (default soil fraction organic matter)
$Fom_{soil(exp)}$ = 1.34% (see Table 9)
$EC_{10(std)}$ = 1.5 mg/kg x 1/1.34 = 1.12 mg/kg

On the basis that the data consists of one short-term result from one trophic level and two long-term results from two additional levels, an assessment factor of 50 has been applied to the lowest reported long-term EC_{10} of 1.12 mg/kg soil dry weight [corrected for organic carbon content] for soil organisms. The $PNEC_{soil}$ is 0.02 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Glutaraldehyde is readily biodegradable and thus does not meet the screening criteria for persistence.

The log K_{ow} for glutaraldehyde at different pH values ranges from -0.36 to -0.80. Thus, glutaraldehyde does not meet the screening criteria for bioaccumulation.

The lowest NOEC value from chronic aquatic toxicity studies is < 0.1 mg/L. Thus, glutaraldehyde meets the screening criteria for toxicity.

The overall conclusion is that glutaraldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 3 [oral]

Acute Toxicity Category 2 [inhalation]

Skin Corrosion Category 1B

Eye Damage Category 1

Respiratory Sensitiser 1A

Skin Sensitiser 1A

STOT Single Exposure Category 3 [respiratory irritation]

Aquatic Acute Category 1

Aquatic Chronic Category 2

The appropriate hazard statements corresponding the GHS classifications are to be added to the SDS, including the non-GHS hazard statement “AUH071: Corrosive to the Respiratory Tract”.

B. Labelling

Danger

C. Pictograms



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

First aid information was obtained from the ECHA REACH database (ECHA).

Eye Contact

Wash immediately and continuously with flowing water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist. Eye wash fountain should be located in immediate work area.

Skin Contact

Take off contaminated clothing. Wash skin with soap and plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice. Wash clothing before reuse. Shoes and other leather items which cannot be decontaminated should be disposed of properly. Safety shower should be located in immediate work area.

Inhalation

Move person to fresh air. If a person is not breathing, call an emergency responder or ambulance, then give artificial respiration; if by mouth-to-mouth use rescuer protection (pocket mask, etc.). Call a poison control centre or doctor for treatment advice. If breathing is difficult, oxygen should be administered by qualified personnel.

Ingestion

If the person is fully alert and cooperative, have the person rinse mouth with plenty of water. In cases of ingestion have the person drink 4 to 10 ounces (120-300 mL) of water. Do not induce vomiting. Do not attempt mouth rinse if the person has respiratory distress, altered mental status, or nausea and vomiting. Call a physician and/or transport to an emergency facility immediately. See Note to Physician. Seek medical attention immediately.

Notes to Physician

Maintain adequate ventilation and oxygenation of the patient. May cause asthma-like (reactive airways) symptoms. Bronchodilators, expectorants, antitussives and corticosteroids may be of help. Glutaraldehyde may transiently worsen reversible airways obstruction including asthma or reactive airways disease. Chemical eye burns may require extended irrigation. Obtain prompt consultation, preferably from an ophthalmologist. If the burn is present, treat as any thermal burn, after decontamination. Due to irritant properties, swallowing may result in burns/ulceration of mouth,

stomach and lower gastrointestinal tract with subsequent stricture. Aspiration of vomitus may cause lung injury. Suggest endotracheal/oesophagal control if lavage is done. Probable mucosal damage may contraindicate the use of gastric lavage. Inhalation of vapours may result in skin sensitisation. In sensitised individuals, re-exposure to very small amounts of vapour, mist or liquid may cause a severe allergic skin reaction. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Have the Safety Data Sheet, and if available, the product container or label with you when calling a poison control centre or doctor, or going for treatment.

Medical Conditions Aggravated by Exposure

Excessive exposure may aggravate pre-existing asthma and other respiratory disorders (e.g., emphysema, bronchitis, reactive airways dysfunction syndrome).

Emergency Personnel Protection

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). If the potential for exposure exists, refer to Section 8 of the Safety Data Sheet for specific personal protective equipment.

B. Fire Fighting Information

Firefighting information was obtained from the ECHA REACH database (ECHA).

Extinguishing Media

Use water fog, carbon dioxide, dry chemical or foam to extinguish combustible residues of this product

Specific Exposure Hazards

This material will not burn until the water has evaporated. Residue can burn. Some components of this product may decompose under fire conditions. The smoke may contain unidentified toxic and/or irritating compounds. Combustion products may include, and are not limited to, carbon monoxide and carbon dioxide.

Special Protective Equipment for Firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots and gloves). Avoid contact with this material during firefighting operations. If contact is likely, change to full chemical resistant firefighting clothing with self-contained breathing apparatus. If this is not available, wear full chemical resistant clothing with self-contained breathing apparatus and fight the fire from a remote location.

C. Accidental Release Measures

Information on accidental release measures was obtained from the ECHA REACH database (ECHA).

Personal Precautions

Use appropriate safety equipment. Evacuate area. Keep upwind of the spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations.

Environmental Precautions

Spills or discharge to natural waterways is likely to kill aquatic organisms. Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Steps to be Taken if Material is Released or Spilt

Avoid making contact with spilt material; glutaraldehyde will be absorbed by most shoes. Always wear the correct protective equipment, consisting of splash-proof mono-goggles, or both safety glasses with side shields and a wraparound full-face shield, appropriate gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilt material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilt material with water to reduce odour, and discharge the rinsate into a municipal or industrial sewer.

Large spills: In the case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious to glutaraldehyde, including rubber boots or shoe protection. Deactivate with sodium bisulphite (2-3 parts [by weight] per part of active substance glutaraldehyde), collect the neutralised liquid and place in a drum for transit to an approved disposal site.

D. Storage and Handling

Information on storage and handling was obtained from the ECHA REACH database (ECHA).

General Handling

Do not get in eyes, on skin, on clothing. Avoid breathing vapour. Do not swallow. Keep container closed. Use with adequate ventilation. Wear goggles, protective clothing and butyl or nitrile gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Other Handling Precautions

Do not spray or aerosolise the undiluted form of the product. Full personal protective equipment (including skin covering and full-face SCBA respirator) is required for dilutions or mixtures of the product used in a spray application.

Storage

Do not store in: Aluminium. Carbon steel. Copper. Mild steel. Iron. Shelf life: Use within 12 Months.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for glutaraldehyde in Australia is 0.1 ppm (0.41 mg/m^3) as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

The information below on exposure controls and personal protection was obtained from the Halliburton Safety Data Sheet (SDS) on ALDACIDE® G ANTIMICROBIAL (revision date: 11-Dec-2014).

Engineering Controls

Use in a well-ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation. If vapours are strong enough to be irritating to the nose or eyes, the TLV is probably being exceeded, and special ventilation or respiratory protection may be required.

Personal Protection Equipment

Respiratory Protection: If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH-certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Full Facepiece Respirator with Organic vapour cartridge with particulate pre-filter.

Hand Protection: Chemical-resistant protective gloves (EN 374). Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480-minute permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness). This information is based on literature references and on information provided by glove manufacturers or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g., temperature). If signs of wear and tear are noticed, then the gloves should be replaced. Manufacturer's directions for use should be observed because of the great diversity of types.

Skin Protection: Butyl coated apron or clothing.

Eye protection: Splash proof chemical mono-goggles or safety glasses with side shield in conjunction with a face shield. Do NOT wear contact lenses.

Other Precautions: Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

For aqueous glutaraldehyde solutions at a concentration that is corrosive (i.e., 30% and higher):

Australia Dangerous Goods

UN3265, Corrosive Liquid, Acidic, Organic, N.O.S. (Contains Glutaraldehyde)

Class 8

Packing Group III

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII.REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ema, M., Itami, T., and Kawasaki, H. (1992). Teratological assessment of glutaraldehyde in rats by gastric intubation. Toxicol. Lett. 63: 147-153.

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Frantz, S.W., Beskitt, J.L., Tallant, M.J., Futrell, J.W., and Ballantyne, B. (1993). Glutaraldehyde: species comparisons of in vitro skin penetrations. J. Toxicol.-Cut. & Ocular Toxicol. 12: 349-361.

Gross, E.A., Mellick, P.W., Kari, F.W., Miller, F.J., and Morgan, K.T. (1994). Histopathology and cell replication responses in the respiratory tract of rats and mice exposed by inhalation to glutaraldehyde for up to 13 weeks. Fundam. Appl. Toxicol. 23: 348-362.

Haseman, J.K., Hailey, J.R., and Morris, R.W. (1998). Spontaneous neoplasm incidences in Fischer 344 rats and B6C3F_1 mice in two-year carcinogenicity studies: A National Toxicology Program update. Toxicol. Pathol. 26: 428-441.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Leung, H.W. (2001). Ecotoxicology of glutaraldehyde: review of environmental fate and effects studies. Ecotoxicol. Environ. Safety 49: 26-39.

Mirsalis, J.S., Tyson, C.K., Steinmetz, K.L., Loh, E.K., Hamilton, C.M., Bakke, J.P., and Spalding, J.W. (1989). Measurement of unscheduled DNA synthesis and S-phase synthesis in rodent hepatocytes following in vivo treatment: testing of 24 compounds. Environ. Mol. Mutagen. 14: 155-164.

Neeper-Bradley, T.L., and Ballantyne, B. (2000). Two-generation reproduction study by dosing with glutaraldehyde in the drinking water of CD rats. J. Toxicol. Environ. Health A 61: 107-129.

NICNAS. (1994). Glutaraldehyde – Full Public Report. National Industrial Chemicals Notification and Assessment Scheme (NICNAS), AGPS, Canberra, Australia.

OECD. (1995). OECD-SIDS document on Glutaraldehyde, CAS No. 111-30-8, UNEP Publications. Accessed at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=b13f2e48-0425-4a8a-b7b8-c04cfaab06e8

Stromberg, P.C. (1985). Large granular lymphocyte leukaemia in F344 rats: Model for human T lymphoma, a malignant histiocytosis and T-cell chronic lymphocytic leukaemia. Am. J. Pathol. 119: 517-519.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P.J. (2007). A review of large granular lymphocytic leukaemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

van Birgelen, A.P.J.M., Chou, B.J., Renne, R.A., Grumbein, S.L., Roycroft, J.H., Hailey, J.R., and Bucher, J.R. (2000). Effects of glutaraldehyde in a 2-year inhalation study in rats and mice. Toxicol. Sci. 55: 195-205.

Van Miller, J.P., Hermansky, S.J., Losco, P.E., and Ballantyne, B. (2002). Chronic toxicity and oncogenicity study with glutaraldehyde dosed in the drinking water of Fischer 344 rats. Toxicol. 175: 177-189.

Vergnes, J.S., and Ballantyne, B. (2002). Genetic toxicology studies with glutaraldehyde. J. Appl. Toxicol. 22: 45-60.

Ward, J.M., Rehm, S., and Reynolds, C.W. (1990). Tumours of the haematopoietic system. In: Pathology of Tumours in Laboratory Animals, Vol. 1, Second Edition (Turusov, V.S., and Mohr, U., Eds.), pp. 625-657, International Agency for Research on Cancer, Lyon, France.

Zissu, D., Bonnet, P., and Binet, S. (1998). Histopathological study in B6C3F1 mice chronically exposed by inhalation to glutaraldehyde. Toxicol. Lett. 95: 131-139.

GLYCERINE
[GLYCEROL]

This dossier on glycerine presents the most critical studies pertinent to the risk assessment of glycerine in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on glycerol (OECD, 2002), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Glycerol

CAS RN: 56-81-5

Molecular formula: $C_3H_8O_3$

Molecular weight: 92.09

Synonyms: Glycerine; glycerin; glycerol; glycyl alcohol; 1,2,3-propanetriol; trihydroxypropane

SMILES: C(C(CO)O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Glycerine[1]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, water-white, viscous, sweet-tasting hygroscopic liquid.	2	ECHA
Melting Point	18.17°C	2	ECHA
Boiling Point	290°C	2	ECHA
Density	1.2611 g/ml or g/cm^3 @ 20°C	2	ECHA
Vapor Pressure	<0.001 mm Hg at room temperature	2	ECHA
Partition Coefficient (log K_{ow})	-1.75 @ 25°C (measured)	2	ECHA

[1] Substance is known to be on the EEA market in nanomaterial form.

Property	Value	Klimisch score	Reference
Water Solubility	Completely miscible @ 25°C	2	ECHA
Flash Point	195.6^{o}C; 177°C; 199°C	2	ECHA
Auto flammability	370°C; 429°C	2	ECHA
Viscosity	1.41 Pa s @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Glycerine is readily biodegradable. It is not expected to bioaccumulate. Based on the estimated K_{oc} value, glycerine is expected to be highly mobile in sediment and soil.

B. Biodegradation

Glycerine was readily biodegradable in an OECD 301D test. Degradation was 57% after 5 days, 84% after 15 days, and 92% after 30 days (OECD, 2002) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for glycerine. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} value from log K_{ow} is 0.1345 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1 L/kg.

D. Bioaccumulation

No bioconcentration studies have been conducted on glycerine. Glycerine is not expected to bioaccumulate based on the experimental log K_{ow} of -1.75 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Glycerine has virtually no acute toxicity by the oral and dermal routes. It is non-irritating to the skin and eye and is not a skin sensitizer. No systemic toxicity was seen in animals repeatedly exposed by the dermal and inhalation routes, but liver effects were seen in rats given very high doses in the diet. Glycerine is not genotoxic. Lifetime dietary studies showed no carcinogenic effects in rats. No reproductive or developmental effects were seen in animals given high doses of glycerine in the diet.

B. Toxicokinetics/Metabolism

Glycerol is an intermediate in carbohydrate and lipid metabolism in living organisms.

C. Acute Toxicity

The oral LD_{50} values are >5,000 to 58,400 mg/kg in rats, 4,250 to 38,000 mg/kg in mice, 7,750 and 10,000 mg/kg in guinea pigs (OECD, 2002). The oral LD_{50} value of 4,250 mg/kg in mice is not consistent with the range of values found in the available literature and is considered unreliable because of the lack of documentation of the study (OECD, 2002).

All rats died following a 2-hour exposure to saturated vapors of glycerine, while there was no mortality when the exposure was for only one hour (ECHA) [Kl. score = 2].

No deaths were seen in rabbits following dermal application for 8 hours under occlusive conditions. The dermal LD_{50} is >18,700 mg/kg (Hine *et al.*, 1953).

D. Irritation

Application of 0.5 ml glycerine to the skin of rabbits for 24 hours under occlusive conditions was not irritating (Weil and Scala, 1971; ECHA). [Kl. score = 2]

Instillation of 0.1 ml glycerine into the eyes of rabbits was non-irritating (Weil and Scala, 1971; ECHA).

E. Sensitization

Male guinea pigs were given ten 0.1 mL injections of a 0.1% solution of synthetic or natural glycerine in isotonic saline every other day over 20 days. Following a two-week period, an 0.05 mL injection was given of the 0.1% glycerine solution. There was no sensitizing response (Hine *et al.*, 1953).

F. Repeated Dose Toxicity

<u>Oral</u>
Male and female rats were given in their feed 0, 5, or 20% glycerine for 90 days. Glycerine samples from different companies were compared in separate groups of animals. Body weight gain was higher in the treated rats compared to the controls. The 20% males had increased liver weights relative to body weights with histopathologic changes of generalized cloudy swelling and hypertrophy of the parenchymal cells. The 20% females showed increased relative liver weights, but had generalized cloudy swelling in the liver. For the liver changes, there were no differences between the three glycerine samples. Relative heart weights were significant reduced in the 20% females from one glycerine sample, and relative kidney weights were increased in the 20% females from another glycerine sample; these changes were not accompanied by histopathological changes. The NOAEL for this study is 5% glycerine in the diet, which corresponds to an estimated daily intake of 4,580 and 6,450 mg/kg-day for males and females, respectively (ECHA). [Kl. score = 2]

Male and female Long-Evans rats were given in their feed 0, 5, 10, or 20% glycerine for two years (the 20% group were for 1 year only). The estimated daily intakes are 0, 2,000, 4,000, and 8,000 mg/kg-day for males; and 0, 2,500, 5,000, and 10,000 mg/kg-day for females. Treatment was discontinued after one year for the 20% animals for reasons that were not stated in the report. Data on mortality and clinical observations were not reported. There was a slight increase in food consumption in the ≥5% group males. No adverse effects were reported in males or females at any dose level. The NOAEL is 20% glycerine in the diet, which corresponds to 8,000 and 10,000 mg/kg-day for males and females, respectively (Hine et al., 1983; ECHA). [Kl. score = 2]

Female rats were given in their drinking water 0, 5% synthetic glycerine, or 5% natural glycerine for 6 months. There were no difference between the two glycerine samples. The treated rats gained more weight over the treatment period than the controls. There were no treatment-related hematological changes, and there were mild treatment-related kidney effects, as indicated by calcified masses in tubules near the junction of the cortex and medulla (Anderson et al., 1950; ECHA). [Kl. score = 2]

Inhalation

Male and female SD rats were exposed by inhalation (nose-only) to 0, 33, 165, or 660 mg/m^3 of aerosolized glycerine 6 hours/day, 5 days/week for 13 weeks. The mass median aerodynamic diameter (MMAD) was <2.0 µm (respirable). The only effect seen was localized irritation of the upper respiratory tract. The NOAEC for systemic toxicity is 660 mg/m^3, the highest exposure concentration tested. The NOAEC for localized effects (irritation) is 167 mg/m^3 (Renne, 1992; ECHA). [Kl. score = 2]

Dermal

Rabbits were given dermal applications of 0.5 to 5.4 ml/kg glycerine 8 hours/day for 45 weeks. No effects including irritation were noted. The NOAEL is 5.4 ml/kg, which is calculated to be 5,040 mg/kg-day (ECHA). [Kl. score = 2]

G. Genotoxicity

In Vitro Studies

The results of the *in vitro* studies on glycerine are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Glycerine

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Haworth *et al.*, 1983; ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Doolittle *et al.*, 1988; ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (CHO cells)		-	2	Doolittle *et al.*, 1988; ECHA
Sister chromatid exchange (human lymphocytes)	-	-	2	Doolittle *et al.*, 1988; ECHA
Unscheduled DNA synthesis (rat hepatocytes)	-	-	2	Doolittle *et al.*, 1988; ECHA
Chromosomal aberrations (CHO cells)	-	-	2	Doolittle *et al.*, 1988; ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available.

H. Carcinogenicity

Oral

Male and female Long-Evans rats were given in their feed 0, 5, 10, or 20% glycerine for two years (the 20% group were for 1 year only). The estimated daily intakes are 0, 2,000, 4,000, and 8,000 mg/kg-day for males; and 0, 2,500, 5,000, and 10,000 mg/kg-day for females. Treatment was discontinued after one year for the 20% animals for reasons that were not stated in the report. Data on mortality and clinical observations were not reported. The tumor incidences were similar between treated and control animals (Hine et al., 1953; ECHA). [Kl. score = 2]

I. Reproductive Toxicity

In a two-generation reproductive toxicity study, male and female rats were dosed by oral gavage with 0 or 20% glycerine solution (in water). There were no treatment-related effects on growth, reproductive performance, fertility, and no histopathological changes in the tissues examined. The NOAEL for this study is 20% glycerine in water, which the daily intake was estimated to be 2,000 mg/kg-day (OECD, 2002; ECHA). [Kl. score = 2]

J. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0, 13.1, 60.8, 282, or 1,310 mg/kg-day glycerine during gestational days 6 to 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,310 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 2]

Pregnant female CD-1 mice were dosed by oral gavage with 0, 12.8, 59.4, 276, or 1,280 mg/kg-day glycerine during gestational days 6 to 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,280 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 2]

Pregnant female Dutch rabbits were dosed by oral gavage with 0, 11.8, 54.8, 254.5, or 1,180 mg/kg-day glycerine during gestational days 6 to 18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,280 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for glycerine follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Liver effects were seen in male and female rats in a 90-day dietary study, with a NOAEL of 5% glycerine in the diet. This dose corresponds to an estimate daily intake of 4,580 and 6,450 mg/kg-day for males and females, respectively (ECHA). In a two-year dietary study, no effects were seen in male or female rats at a dose of 20% glycerine in the diet. It should be noted, however, that the treatment at the dietary level of 20% was for only one year, while the lower doses (5 and 10%) were for two years. No liver effects were noted at any dose level. The NOAEL for the two-year dietary study is the 20% dietary level which corresponds to estimated daily intakes of 8,000 and 10,000 mg/kg-day, for males and females, respectively (Hines et al., 1953; ECHA).

The NOAEL of 4,580 mg/kg-day from the males rats in the 90-day dietary study will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 4,580/(10 x 10 x 1 x 10 x 1) = 4,580/1,000 = 4.6 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (4.6 x 70 x 0.1)/2 = 16 mg/L

B. Cancer

Glycerine was not carcinogenic to rats in a two-year dietary study. Therefore, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Glycerine does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Glycerine is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies on glycerine.

Table 3: Acute Aquatic Toxicity Studies on Glycerine

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LC_{50}	54,000	2	ECHA
Sheepshead minnow	96-h LC_{50}	>11,000	2	ECHA

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Daphna magna	24-h EC_{50}	>10,000	2	ECHA
Scenedesmus quadricauda	8-d EC_0	>10,000	2	Bringmann, 1980; OECD, 2002

Chronic Studies
No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for glycerine follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels, although the data on algae cannot be used for determining a PNEC value. Acute E(L)C_{50} values are available for fish (>11,000 mg/L) and *Daphnia* (>10,000 mg/L). On the basis that the data consists of short-term results from two trophic levels, an assessment factor of 100 has been applied to the lowest reported E(L)C_{50} value of 10,000 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 100 mg/L.

PNEC sediment
There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 64 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.82/1280) \times 1000 \times 100$
$= 64$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.04/1000 \times 2400]$
$= 0.82$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 1 \times 0.04$
$= 0.04$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for glycerol calculated from EPISUITE™ using MCI is 1 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 1.3 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.02/1500) \times 1000 \times 100$
$= 0.13$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1 \times 0.02$
$= 0.02$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for glycerol calculated from EPISUITE™ using MCI is 1 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Glycerine is readily biodegradable and thus does not meet the screening criteria for persistence.

No bioconcentration studies are available for glycerine. The measured log K_{ow} for glycerine is -1.75; thus glycerine does not meet the screening criteria for bioaccumulation.

The acute $E(L)C_{50}$ values for glycerine in fish, invertebrates, and algae are >1 mg/L. Thus glycerine does not meet the screening criteria for toxicity.

Therefore, glycerine is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus for fire fighting.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Ensure adequate ventilation. Do not breathe vapors, mists, or gas.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Soak up with inert absorbent material and dispose of as hazardous waste.

D. Storage And Handling

General Handling
No special measures necessary provided product is used correctly.

Other Handling Precautions
Avoid inhalation of vapor or mist.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for glycerine.

Engineering Controls
None

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended.

F. Transport Information

Glycerol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Anderson, R.C., Harris, P.N., and Chen, K.K. (1950). Toxicological studies on synthetic glycerin. J. Am. Pharm. Assoc. 39: 583-585.

Bringmann, G., and Kuehn, R. (1980). Comparison of the toxicity thresholds of water pollutants to bacteria, algae, and protozoa in the cell multiplication inhibition test. Water. Res. 14: 231-241.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Doolittle, D., Lee, D.A., and Lee, C.K. (1988). The genotoxic activity of glycerol in an *in vitro* test battery. Food Chem. Toxicol. 26: 631-635.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Haworth, S. *et al.* (1983). Salmonella mutagenicity test results for 250 chemicals. Environ. Mutagen. Suppl. 1: 3-142.

Hine, C.H., Anderson, H.H., Moon, H.D., Dunlap, M.K., and Morse, M.S. (1953). Comparative toxicity of synthetic and natural glycerin. AMA Arch. Ind. Hyg. Occup. Med. 7: 282-291.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2002). SIDS Initial Assessment Report (SIAR) and IUCLID Data Set on Glycerol (CAS No. 56-81-5), UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/56815.pdf.

Renne, R. (1992). 2-Week and 13-week inhalation studies of aerosolized glycerol in rats. Inhal. Toxicol. 4: 95-111.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Weil, C.S., and Scala, R.A. (1971). Study of intra- and interlaboratory variability in the results of rabbit eye and skin irritation tests. Toxicol. Appl. Pharmacol. 19: 276-360.

GUAR GUM

This dossier on guar gum (CAS RN 9000-30-0) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the chemistry database PubChem. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): disodium;[[[5-(6-aminopurin-9-yl)-3-hydroxyoxolan-2-yl]oxy-methoxyphosphoryl]oxy-oxidophosphoryl] hydrogen phosphate

CAS RN: 9000-30-0

Molecular weight: 535.15 g/mol; 200,000 to 300,000 daltons (Glickman, 1969)

Molecular formula: $C_{10}H_{14}N_5Na_2O_{12}P_3$

Synonyms: GU-052, guar flour, guaran, gum guar, slocose

SMILES:: COP(=O)(OC1C(CC(O1)N2C=NC3=C(N=CN=C32)N)O)OP(=O)([O-])OP(=O)(O)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Guar Gum

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Off-white to yellowish-white powder	-	PubChem
Vapour Pressure	Negligible	-	PubChem
Water Solubility	< 1 g/L @ 20°C (insoluble)	-	PubChem

III. ENVIRONMENTAL FATE PROPERTIES

Guar gum is a carbohydrate polymer consisting of D-mannose and D-galactose sugars from the guar plant or cluster bean. As a high molecular weight polysaccharide polymer, guar gum is expected to have a negligible vapour pressure. If released to air, a negligible vapour pressure indicates guar gum will exist solely in the particulate phase in the atmosphere. Particulate-phase guar gum will be removed from the atmosphere by wet and dry deposition. If released to soil, guar gum is expected to have no mobility since it is a polymer that binds strongly with soil particles. Volatilisation from moist soil surfaces is not expected to be an important fate process based upon a negligible Henry's Law constant. Likewise, guar gum is not expected to volatilise from dry soil surfaces based upon its vapour pressure. If released into water, guar gum is expected to adsorb to suspended solids and sediment (PubChem). Half-life data was not available.

Guar gum is expected to readily undergo microbial biodegradation in the environment (on the basis that it is a polysaccharide and expected to be readily biodegradable), and the potential to bioaccumulate in organisms is considered to be low (DoEE, 2017 and USEPA, 2005).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Guar gum exhibits very low acute toxicity by the oral route. It is non-irritating to the skin and minimally irritating to the eyes. Repeated dose toxicity studies in rats showed minimal toxicity from exposure to guar gum in the diet. Guar gum is not genotoxic or carcinogenic. Oral exposure to guar gum did not affect fertility in rats; nor was there any indication of developmental toxicity in either rats or mice.

NICNAS has assessed Guar Gum in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,060 mg/kg (Graham *et al.*, 1981) [Kl. Score = 2].

C. Irritation

Guar gum is non-irritating to the skin and minimally irritating to the eyes (McCarty *et al.*, 1990). Nonetheless, ECHA warns that the substance may cause serious eye irritation.

D. Sensitisation

There were reports of workers sensitised to guar gum in a carpet-manufacturing plant. Immediate skin reactivity to guar gum was observed in 8 out of 162 employees, and 11 of 133 participants had serum IgE antibodies to guar gum. These findings are difficult to interpret since carbohydrates, such as guar gum, are generally not associated with allergenicity (Malo, 1990).

E. Repeated Dose Toxicity

Oral

Male and female Osborne-Mendel rats were given diets containing 0, 1, 2, 4, 7.5, or 15% guar gum for 91 days. The average daily intakes are: 0; 580; 1,187; 2,375; 4,561 and 10,301 mg/kg/day for males; and 0; 691; 1,362; 2,762; 5,770 and 13,433 mg/kg/day for females. There were no deaths during the study. Body weights were significantly decreased in the ≥1% females and the ≥7.5% males; biologically significant changes (>10%) were seen in the 7.5% females and the 15% males. Liver weights were decreased in the ≥1% dietary groups. Kidney weights were decreased in the ≥7.5% dietary groups and were borderline significant in the 4% group. The 15% group males had reduced bone marrow cellularity; although the level was within normal limits, several of the rats were at the lower end of the normal range.

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9000-30-0%2C+

The NOAEL for this study is 4% in the diet or 2,762 mg/kg/day based on reduced body weights in the female rats (Graham *et al.*, 1981) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0; 6,300; 12,500; 25,000; 50,000 or 100,000 ppm guar gum for 13 weeks. Mean body weights were decreased in the 100,000 ppm male rats and in the ≥50,000 ppm female mice. A dose-related decrease in feed consumption was observed for male and female rats; male and female mice were comparable or higher than that of controls. There were no compound-related clinical signs or histopathological effects. The NOAELs for this study are 50,000 and 25,000 ppm for rats and mice, respectively. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs corresponds to 2,500 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks. Mean body weights of the high-dose females were lower than those of the controls after week 20 for mice and week 40 for rats. No compound-related clinical signs or adverse effects on survival were observed. Feed consumption by dosed rats and mice of either sex was lower than that of controls. There were no non-neoplastic histopathological effects in either rats or mice that were treatment-related. The NOAEL for both rats and mice is 25,000 ppm. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs correspond to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

Guar gum was not mutagenic to *S. typhimurium* strains TA 97, TA 98, TA 100, TA 102, TA 104, TA 1535, TA 1537, and TA1538 in the presence or absence of metabolic activation (Zeiger *et al.*, 1992) [Kl. Score = 2].

In Vivo Studies

Guar gum was inactive in a rat bone marrow cytogenetic assay at doses up to 5,000 mg/kg (Johnson *et al.*, 2015) Kl. Score = 4].

In a rat dominant lethal mutation test, rats were dosed by oral gavage with either a single or multiple doses of up to 5,000 mg/kg guar gum. There was no indication of a mutagenic effect by guar gum (Lee *et al.*, 1983) [Kl. Score = 2].

G. Carcinogenicity

Male and female F344 rats were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. There were increased incidences of

adenomas of the pituitary in male rats and pheochromocytomas of the adrenal medulla in female rats that were statistically significant, but these differences were considered to be unrelated to guar gum administration. When pituitary adenomas or carcinomas and when pheochromocytomas or malignant pheochromocytomas were combined, the statistical differences disappeared. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for F344 rats (NTP, 1982) [Kl. Score = 2].

Male and female $B6C3F_1$ mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. Hepatocellular carcinomas occurred in treated male mice at incidences that were significantly lower than that in controls. The combined incidence of male mice with either hepatocellular adenomas or carcinomas was also significantly lower in the high-dose group. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for $B6C3F_1$ mice (NTP, 1982) [Kl. Score = 2].

H. Reproductive Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intakes for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. Fertility was unaffected by treatment. There were slightly fewer corpora lutea and implantations in the 15% dietary group, but implantation efficiency was unaffected. The NOAEL for reproductive toxicity is 5,200 mg/kg/day (Collins *et al.*, 1987) [Kl. Score = 2].

I. Developmental Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intake for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. There were no deaths during the study. In the 15% group, the number of viable foetuses per litter were slightly reduced but was not statistically significantly different from controls. The authors indicated that the reduction may have been an effect of the decreased number of corpora lutea because the number of resorptions was unaffected in this treatment group. There was no treatment-related effect on foetal development or sex distribution, and there were no teratogenic effects (Collins *et al.*, 1987) [Kl. Score = 2].

Pregnant female rats were dosed by oral gavage with 0, 9, 42, 200 or 900 mg/kg guar gum on GD 6 to 15. There was no maternal or developmental toxicity at any dose level. The NOAEL for maternal and developmental toxicity is 900 mg/kg/day (FDRL, 1973) [Kl. Score = 2].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 8, 37, 170, or 800 mg/kg guar gum on GD 6 to 15. A significant number of deaths (6 out of 29) occurred in the 800 mg/kg dose group. There were indications of maternal toxicity in the surviving high-dose dams. There was no developmental toxicity at any dose level. The NOAELs for maternal and developmental toxicity are 170 and 800 mg/kg/day, respectively (FDRL, 1973) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for guar gum follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

In a two-year NTP chronic bioassay, female rats and mice given 50,000 ppm guar gum in their feed had lower body weights. There were no treatment-related non-neoplastic lesions in either rats or mice. The NOAEL for this study is 25,000 ppm for rats and mice, which corresponds to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice.

The NOAEL of 1,250 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 1,250/(10 x 10 x 1 x 1 x 1) = 1,250/100 = 13 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (13 x 70 x 0.1)/2 = 46 mg/L

B. Cancer

Guar gum was not carcinogenic to rats or mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Guar gum does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Guar gum is a polysaccharide polymer. It has low acute toxicity concern for fish but exhibits moderate acute toxicity to invertebrates (*Daphnia*).

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} for *Oncorhynchus mykiss* is 218 mg/L (Biesinger *et al.*, 1976) [Kl. Score = 2].

The 48-hour and 96-hour LC_{50} values for *Daphnia magna* are 42 mg/L and <6.2 mg/L, respectively (Biesinger *et al.*, 1976) [Kl. Score = 2].

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for guar gum follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. The acute LC_{50} values are available for fish (218 mg/L) and *Daphnia* (<6.2 mg/L). No chronic studies are available. On the basis that the data consists of acute studies from two trophic levels, an assessment factor of 1,000 has been applied to the lowest reported LC_{50} value of 6.2 mg/L for *Daphnia*. The $PNEC_{water}$ is 0.006 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{sediment}$ and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{soil}$ and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Guar gum is a naturally occurring polysaccharide from the guar plant or cluster bean; it expected to be readily biodegradable. Thus it is not expected to meet the screening criteria for persistence.

The potential to bioaccumulate in organisms is considered to be low. Thus guar gum is not expected to meet the criteria for bioaccumulation.

There are no adequate chronic aquatic toxicity studies available on guar gum. The acute LC_{50} values for guar gum are >1 mg/L in fish and invertebrates. Therefore, guar gum does not meet the screening criteria for toxicity.

The overall conclusion is that guar gum is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Aquatic Toxicity Category 2

B. Labelling

Warning!

According to the classification provided by companies to ECHA in CLP notifications, this substance causes serious eye irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Remove contaminated clothing. Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

Notes to Physician

May cause asthma-like (reactive airways) symptoms.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus for fire fighting.

C. Accidental Release Measures

Personal Precautions

Avoid dust formation.

Environmental Precautions

No special environmental precautions required.

Steps to be Taken if Material is Released or Spilled

Sweep up and dispose in suitable, closed containers.

D. Storage And Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard specifically for guar gum.

Engineering Controls

Ensure adequate ventilation.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Handle with gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Guar gum is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Biesinger, K.E., Lemke, A.E., Smith, W.E., and Tyo, R.M. (1976). Comparative toxicity of polyelectrolytes to selected aquatic animals. J. Water Pollut. Control Fed. 48: 183-187; cited in U.S. EPA ECOTOX database.

Collins, T.F.X., Welsh, J.J., Black, T.N., Graham, S.L., and O'Donnell, M.W., Jr. (1987). Study of the teratogenic potential of guar gum. Food Chem. Toxicol. 25: 807-814.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Food and Drug Research Laboratories, Inc. [FDRL]. (1973). Teratologic evaluation of FDA 71-16 (guar gum) in mice, rats, hamsters, and rabbits. Final report prepared under DHEW contract No. FDA 71-260. Maspeth, NY. NTIS No. PB-223-819/4; cited in CIR (2015).

Glickman M. (1969). Gum technology in the Food Industry, pp. 590, Academic Press, New York; cited in Yoon *et al.* (1998).

Graham, S.L., Arnold, A., Kasza, L., Ruffin, G.E., Jackson, R.C., Watkins, T.L., and Graham, C.H. (1981). Subchronic effects of guar gum in rats. Fd. Cosmet. Toxicol. 19: 287-290.

Johnson, W., Jr., Heldreth, B., Bergfeld, W.F., Belsito, D.V., Hill, R.A., Klaassen, C.D., Liebler, D.C., Marks, J.G., Jr., Shank, R.C., Slaga, T.J., Snyder, P.W., and Andersen, F.A. (2015). Safety assessment of galactomannans as used in cosmetics. Int. J. Toxicol. 34(Suppl. 1): 35S-65S.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lee, W.R., Abrahamson, S., Valencia, R., Von Halle, E.S., Wuergler, F.E., and Zimmering, S. (1983). The sex-linked recessive lethal test for mutagenesis in *Drosophila melanogaster*. A report of the U.S. Environmental Protection Agency Gene-Tox Program. Mutat. Res. 123: 183-279.

Malo, J.L., Cartier, A., L'Archevêque, J., Ghezzo, H., Soucy, F., Somers, J., and Dolovich, J. (1990). Prevalence of occupational asthma and immunologic sensitization to guar gum among employees at a carpet-manufacturing plant. J. Allergy Clin. Immunol. 86: 562-569.

McCarty, J.D., Weiner, M., Freeman, C., Aguinaldo, E.R., and Fletcher, M.J. (1990). Primary skin and ocular irritation studies on five food additive plant gums. J. Am. Coll. Toxicol. 1(1): 50-51.

NTP. (1982). NTP Technical Report on the Carcinogenesis Bioassay of Guar Gum (CAS No. 9000-30-0) in F344 Rats and B6C3F_1 Mice (Feed Study), National Toxicology Program, Research Triangle Park, NC.

PubChem. PubChem open chemistry database: https://pubchem.ncbi.nlm.nih.gov

United States Environmental Protection Agency [USEPA]. (2005). Science Assessment for Hydroxypropyl Guar Gum, Lower Risk Pesticide Chemical Focus Group, Office of Prevention, Pesticides and Toxic Substances, US Environmental Protection Agency. Accessed: http://www.epa.gov/opprd001/inerts/hydroxypropyl.pdf

Zeiger, E., Anderson, B., Haworth, S., Lawlor, T., and Mortelmans, K. (1992). Salmonella mutagenicity tests: V. Results from the testing of 311 chemicals. Environ. Mol. Mutagen. 21: 2-141.

HYDROCHLORIC ACID

This dossier on hydrochloric acid presents the most critical studies pertinent to the risk assessment of hydrochloric acid in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from OECD-SIDS documents (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Chlorane

CAS RN: 7647-01-0

Molecular formula: HCl

Molecular weight: 36.46 g/mol

Synonyms: Hydrochloric acid; HCl; chlorane; hydrogen chloride; muriatic acid; chlorohydric acid

SMILES: Cl

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Hydrochloric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless to slightly yellow gas of fuming liquid with pungent, irritating odour.	2	ECHA
Melting Point	-114.22°C	2	ECHA
Boiling Point	-85°C	4	ECHA
Density	1.639 kg/m^3 @ 0°C (gas) 1190 kg/m^3 @ 15°C (liquid)	4	ECHA
Vapour Pressure	4,104 kPa 4,723 kPa @ 25°C	4	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble	4	ECHA
Viscosity	1.7 x 10^{-6} m^2s @ 20°C	1	ECHA

Hydrochloric acid can exist in a gaseous phase at room temperature and pressure. Hydrochloric acid is also very soluble in water and is a strong acid that dissociates completely in water to hydrogen (H^+) and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility, hydrochloric acid will be found predominantly in the aquatic environment where it dissociates completely to hydrogen (H^+) and chloride (Cl^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of hydrochloric acid to an aquatic ecosystem may decrease the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of hydrochloric acid into the aquatic environment from the use of HCl could potentially increase the chloride concentration and decrease the pH in the aquatic environment. Table 2 shows the amount of hydrochloric acid that would need to be added to bicarbonate solutions to obtain pH values of 6.0 and 4.0. The UNEP (1995) study reported that the 10th percentile, mean and the 90th percentile of bicarbonate concentrations in 77 rivers in North America, South America, Asia, Africa, Europe and Oceania were 20, 106, and 195 mg/L, respectively. The data show that the decrease in pH depends on the buffer capacity (bicarbonate concentration) of the receiving water. The calculated values in Table 2 were confirmed experimentally.

Table 2: Buffer capacity to maintain the pH based on bicarbonate concentration from UNEP monitoring data (de Groot and van Dijk, 2002; taken from OECD, 2002b)

Initial concentration of HCO_3^-	Final pH	Concentration of HCl required to obtain the final pH value
		Calculated (mg/L)
20 mg/L HCO_3^- (10th percentile 77 rivers)	6.0	8.28
	4.0	11.9
106 mg/L HCO_3^- (mean value of 77 rivers)	6.0	43.9
	4.0	63.2
195 mg/L HCO_3^- (90th percentile 77 rivers)	6.0	80.7
	4.0	116.3

H^+ and Cl^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002a,b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Hydrochloric acid is a corrosive liquid. Depending on the concentration, aqueous solutions of hydrochloric acid (HCl) are either corrosive, irritating or non-irritating to the skin, eyes and gastrointestinal tract. Vapours from aqueous solutions of HCl can cause respiratory irritation. HCl is not a skin sensitiser. Subchronic inhalation studies show localised irritation to the upper respiratory tract of rats and mice, but no systemic toxicity. No repeated dose toxicity studies have been conducted by the oral route. Positive findings have been reported in some *in vitro* genotoxicity studies, which are considered to be the result of the pH change in the test system. A lifetime inhalation study showed no carcinogenicity in rats exposed to HCl. No adequate reproductive or developmental studies have been conducted on HCl.

B. Acute Toxicity

The oral LD_{50} values in rats were reported to be 238 to 277 mg/kg and 700 mg/kg (OECD, 2002a,b) [Kl. scores = 2 and 4, respectively].

The lethal dose by dermal exposure is > 5,010 mg/kg for rabbits (OECD 2002a,b) [Kl. score = 4].

The LC_{50} values in rats for HCl gas are 40,989 and 4,701 ppm for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2]. The LC_{50} values in rats for HCl aerosol are 31,008 and 5,666 ppm (45.6 and 8.3 mg/L) for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2].

C. Irritation

Application of a 37% aqueous solution of HCl for 1 or 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 2]. Application of 0.5 mL of a 17% solution of aqueous solution of HCl for 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 3]. Moderate skin irritation was observed in rabbits following an application of 0.5 mL of a 3.3% aqueous solution of HCl for five days; no irritation was observed with 0.5 mL of a 1% aqueous solution (OECD, 2002a,b) [Kl. score = 2]. In humans, an aqueous solution of 4% of HCl was slightly irritating, while a 10% solution was sufficiently irritating to be classified as a skin irritant (OECD, 2002a,b).

Instillation of 0.1 mL of a 10% aqueous solution of HCl to the eyes of rabbits resulted in severe eye irritation (ECHA) [Kl. score = 2]. Instillation of 0.1 mL of a 5% solution of HCl produced corneal opacity, iridial lesions, conjunctival redness and chemosis in 3/3 animals at 1 hour and at day one post-instillation. There was no recovery in any animal and the study was terminated on day two (ECHA) [Kl. score = 1].

D. Sensitisation

Hydrochloric acid was not a skin sensitiser in a guinea pig maximisation test (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

No adequate studies were located.

Inhalation

Male and female SD rats and F344 rats were exposed by inhalation to 0, 10, 20, or 50 ppm 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm male F344 rats. There were no treatment-related effects on the haematology or clinical chemistry parameters or urinalysis. At study termination, heart, kidney and testes weights were increased in the 100 and/or 50 ppm groups; these changes were considered to be mainly related to the treatment-related effect on body weight. Histopathological examination showed minimal to mild rhinitis in the ≥ 20 ppm dose groups of both strains of rats (both sexes). The NOAELs for systemic toxicity and localised irritation (site-of-contact) are 20 and 10 ppm, respectively (ECHA) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 10, 20 or 50 ppm HCl, 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm groups. At study termination, absolute liver weights were decreased in the 50 ppm males. Histopathologic examination showed only eosinophilic globules in the nasal epithelium in the 50 ppm animals. The NOAEL for this study is 20 ppm (ECHA) [Kl. score = 1].

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium (ECHA) [Kl. score = 2].

Dermal

No studies were located.

F. Genotoxicity

In Vitro Studies

Table 3 presents the *in vitro* genotoxicity studies on hydrochloric acid.

Table 3: *In Vitro* Genotoxicity Studies on Hydrochloric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	+	2	ECHA
Chromosomal aberration (CHO cells)	+	+	2	ECHA
Saccharomyces cerevisiae (mitotic recombination	-	-	2	ECHA
E. coli W3110 (pol A+) and P3078 (pol A-) repair assay	-	-	2	ECHA

* +, positive; -, negative

In the mouse lymphoma assay, the mutant frequency increased as the pH was lowered to 6.5 to 6.0 (from increased HCl) in the presence of metabolic activation. A decrease in pH from the addition of HCl to the medium also resulted in clastogenic effects to CHO cells in the absence or presence of metabolic activation. The positive findings in these two studies are considered to be the result of the pH change in the test media.

In Vivo Studies

No adequate studies were located.

G. Carcinogenicity

Oral

No studies were located.

Inhalation

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium. There was no increased incidence of tumours in the HCl-treated rats compared to controls (ECHA) [Kl. score = 2].

H. Reproductive Toxicity

No studies were located.

I. Developmental Toxicity

No adequate studies were located.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Repeated dose, reproductive and developmental toxicity studies by the oral route have not been conducted on hydrochloric acid. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of hydrochloric acid, which would limit the amount of absorbed HCl. Hydrochloric acid dissociates to hydrogen and chloride ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, an oral toxicological reference and drinking water guidance values were not derived from hydrochloric acid.

The Australian drinking water guideline values for pH (6.5 to 8.5) and chloride (250 ppm, aesthetics) may be applicable (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Hydrochloric acid does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The hazard of hydrochloric acid for aquatic organisms is caused by the hydrogen ion (H^+). The toxicity values in terms of mg/L are not relevant because of the varying buffering capacity of different test systems and different aquatic ecosystems.

B. Aquatic Toxicity

Acute Studies

The acute aquatic toxicity studies on hydrochloric acid are listed in Table 4.

Table 4: Acute Aquatic Toxicity Studies on Hydrochloric Acid

Test Species	Endpoint	Results	Klimisch score	Reference
Lepomis macrochirus	96-hour LC_{50}	pH 3.25 – 3.5 (20 mg/L)	2	ECHA; OECD 2002a,b
Daphnia magna	48-hour EC_{50}	pH 4.92 (0.45 mg/L)	1	ECHA
Chlorella vulgaris	72-hour EC_{50} 72-hour EC_{10}	pH 4.7 [growth rate] (0.73 mg/L) PH 4.7 (0.364 mg/L)	1	ECHA

Chronic Studies

No chronic studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

PNEC values were not derived from hydrochloric acid because factors such as the buffer capacity, the natural pH and the fluctuation of the pH are very specific for a certain ecosystem.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Hydrochloric acid is an inorganic salt that dissociates completely to hydrogen and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both hydrogen and chloride ions are also ubiquitous and are present in water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Hydrogen and chloride ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, hydrochloric acid is not expected to bioaccumulate.

No chronic toxicity data exist on hydrochloric acid. The acute EC_{50} values are > 1 mg/L in fish, < 1 mg/L for invertebrates and algae. Thus, hydrochloric acid meets the screening criteria for toxicity.

The overall conclusion is that hydrochloric acid is a PBT substance based on toxicity to invertebrates and algae.

IX. CLASSIFICATION AND LABELLING

A. Classification

For HCl concentrations of >25%:

- Metal Corrosive Category 1
- Skin Corrosive 1B
- STOT SE Category 3 [Respiratory irritant]

In addition to the hazard statements corresponding to the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

According to the classification provided by companies to ECHA in REACH registrations this substance causes severe skin burns and eye damage, is toxic if inhaled, may damage fertility or the unborn child, causes serious eye damage, may cause damage to organs through prolonged or repeated exposure, may be corrosive to metals and may cause respiratory irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

<u>Skin Contact</u>

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of the body with soap and fresh water. Get medical attention immediately.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device. Give artificial respiration if the victim is not breathing. Get medical attention immediately.

Ingestion

Rinse mouth and lips with plenty of water if a person is conscious. Do not induce vomiting. Do not use mouth-to-mouth method if the victim ingested the substance. Obtain medical attention immediately if ingested.

Notes to Physician

Treat as corrosive due to pH of the material. All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use dry chemical, carbon dioxide, water spray or fog, or foam.

Specific Exposure Hazards

Containers may explode when heated. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following materials: halogenated compounds, may release dangerous gases (chlorine).

Special Protective Equipment for Firefighters

Structural firefighter's protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible. Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Wear positive pressure self-contained breathing apparatus (SCBA). Move containers from the fire area if you can do it without risk.

C. Accidental Release Measures

Personal Precautions

Ventilate enclosed areas. Do not walk through spilt material. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours, or spray. Do not get in eyes, on skin, or on clothing.

Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

Steps to be Taken if Material is Released or Spilt

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). As an immediate precautionary measure, isolate spill or leak area for at least 50 meters in all directions. Keep unauthorised personnel away. Stay upwind. Keep out of low areas. Do not get water inside container.

D. Storage and Handling

General Handling

Handle and open container with care. Use only with adequate ventilation. Keep away from heat. Use caution when combining with water. DO NOT add water to corrosive liquid, ALWAYS add corrosive liquid to water while stirring to prevent the release of heat, steam and fumes. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours or spray. Do not get in eyes, on skin or on clothing. Do not ingest. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

Storage

Keep contain tightly closed. Store in a cool, dry, well-ventilated place. Keep away from incompatible materials. Keep from direct sunlight. Separate from alkalis. Do not store above 49°C/120°F.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for hydrochloric acid in Australia is 5 ppm (7.5 mg/m^3 as a peak limitation, with a sensitisation notation). A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection is based on known or anticipated exposure levels, the hazard of the product and the safe working limits of the selected respirator.

Hand Protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for

any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Skin Protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling hydrochloric acid.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Australian Dangerous Goods

UN 1789 (HYDROCHLORIC ACID)

Class: 8

Packing Group: II or III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

de Groot, W.A., and van Dijk, N.R.M. (2002). Addition of hydrochloric acid to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals, Study No. A SOL.S.027; cited in OECD 2002a,b.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2002a). IUCLID Data Set for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

Hydrotreated light petroleum distillate

This dossier on hydrotreated light petroleum distillate presents the most critical studies pertinent to the risk assessment of this substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

A complex combination of hydrocarbons obtained by treating a petroleum fraction with hydrogen in the presence of a catalyst. It consists of hydrocarbons having carbon numbers predominantly in the range of C9 through C16 and boiling in the range of approximately 150°C to 290°C (302°F to 554°F).

Chemical Name: Hydrotreated light petroleum distillate

CAS RN: 64742-47-8

Molecular formula: C48H94

Molecular weight: (UVCB)

SMILES: CC(C)C1=CC=C(C=C1)C(C)C.CCCCCCCCCCCCCCCCCC.CCCCCCCCCC(C)(C)CCCCCC

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Fatty Acids, C8-C16, 2-Ethylhexyl Esters

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid	2	ECHA
Melting Point	The study did not need to be conducted because the freezing point is below -20°C. Data from CONCAWE 1994 shows that the pour point range is from -49°C for straight run kerosene.	1	ECHA
Boiling Point	-90 to 320°C.	-	-
Density	0.77 to 0.85 g/cm3 at 15 deg C	2	ECHA

Property	Value	Klimisch score	Reference
Vapor Pressure	<1 to 3.7 kPa at 37.8 °C	2	ECHA
Partition Coefficient (log K_{ow})	>10*	2	ECHA
Water Solubility	3.718e-018*	2	ECHA
Flash Point	29 - 70°C	1	ECHA
Auto flammability	220 - 250°C (for kerosenes)	2	ECHA
Viscosity	0.00164Pa.s@ 20°C	2	ECHA

*Calculated from KOWWIN v 1.67 in EPISUITE™ v. 4.00 (EPA, 2017). Due to the fact that this substance is a long-chain hydrocarbon which exceeds the applicability domain of KOWWIN, the value for log K_{ow} is reported with restrictions. The applicability domain covers log K_{ow} up to 10 (maximum), so these values should be given as log K_{ow} >10. The concrete value is reported to show the high lipophilic nature of the substance.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Representative substances are expected to be readily biodegradable. They have a low potential to bioaccumulate. They are highly insoluble in water and have high adsorption potential. While sediment and soil are expected to be the main targets for environmental distribution, biodegradation potential is expected to offset sorption In fact, fugacity modeling suggest that accumulation in sediment is expected to be several orders of magnitude less than 1%, relative to soil, water and air compartments.

B. Biodegradation

Kerosenes are readily to inherently biodegradable. In the supporting OECD 301 study, naphtha solvents were readily biodegraded in 28 days but not within the 10-day window. The mean of three samples was 61% theoretical biological oxygen demand on Day 28 (Shell, 1997). In a valid OECD 301F supporting study Kerosene Mid-Blend was not considered readily biodegradable in 28 days, with less than 60% degradation on day 28 (58.6%). However, according to EPA guidance for biodegradability, it is considered inherently biodegradable because significant degradation occurred (Mobil, 1999). On the basis of this and the known properties of hydrocarbons in the range C9 to C16, in their environmental classification report CONCAWE considered that kerosenes are not readily biodegradable; but as they can be degraded by microorganisms, they are regarded as being inherently biodegradable (CONCAWE, 2001).

C. Environmental Distribution

<u>Adsorption/desorption</u>

No experimental studies are available on the substance. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} values for a similar substance is 1E10 from the molecular connectivity index (MCI) method and

D. Bioaccumulation

No experimental studies are available on the substance. Using BCFBAF in EPISUITE™, the estimated BCF of a representative substance is 0.893 L/kg based on the Arnot-Gobas model that includes biotransformation and upper trophic. Thus, bioaccumulation is not expected (ECHA). [Kl. score = 2]

IV. HUMAN HEALTH HAZARD ASSESSMENT

Specific information on the substance can be found in the ECHA database under fatty acids, C8-C16, 2-ethylhexyl esters (CAS No. 135800-37-2), as well as under 2-ethylhexyl laurate (CAS No. 20292-08-4).

A. Summary

The substance has low acute toxicity by the oral and dermal route. It is not irritating to the skin and eyes, but it is a skin sensitiser. Aside from minor changes in body weight, no adverse effects were seen in animals given repeated doses by the oral route. The substance is not genotoxic when tested in both *in vitro* and *in vivo* assays. There is no indication that this substance will cause malformations or have an adverse effect on reproduction and development. This information was derived in part from products of similar structure or composition.

B. Toxicokinetics/metabolism

The studies of the pharmacokinetics (i.e. absorption, distribution, metabolism and excretion) of kerosene are scarce. There are some *in vitro* and *in vivo* studies available on jet fuels. However, because jet fuel is a complex mixture, these studies use certain constituents of jet fuels as marker compounds to describe the total jet fuel's pharmacokinetics. There are more data available for a number of kerosene constituents, and these can be used as a basis for understanding the pharmacokinetics of kerosene as a whole. There are three ways in which humans are exposed to kerosene: by inhalation; ingestion; and, dermal contact. Due to the relatively low volatility of kerosene and jet fuels, dermal exposure can be a more important route of exposure than exposure via inhalation. During many operations involving aircraft fuel tanks there is a significant potential for dermal exposure. Ingestion occurs primarily as a consequence of incidental ingestion.

Groups of five male C3H mice were dosed with a single dermal application of 15 or 60 µL kerosene (30% straight-run hydrotreated and 70% hydrocracked kerosene) spiked with radiolabeled naphthalene or tetradecane, and sacrificed after 96 h exposure (Mobil, 1994). Another group of five male C3H mice were exposed by air to the same compounds and doses in a metabolism cage to determine passive inhalation. The results of the dermal exposure show that 5% of the labelled tetradecane and 15% of the labelled naphthalene were absorbed over 96 h. The inhalation experiments showed that 2.8% of the labelled naphthalene was bioavailable. Comparison of these data with a similar dataset obtained with a 25% concentration of the test

compounds diluted in mineral oil, revealed that dilution did not affect the absorption of the test compound.

Four groups of eight male Sprague-Dawley rats were exposed to 1, 4, 8,or 16 mL kerosene through the abdominal skin for 2 h at a skin area of 4, 8, 16 or 64 cm2, respectively (Tsujino et al., 2003). Before, during and after the experiment, blood samples were taken and analysed for trimethylbenzenes and aliphatic hydrocarbons. Trimethylbenzenes were detectable in blood within 5-20 min and showed a dose dependent absorption. High concentrations of aliphatic hydrocarbons were detected in the exposed skin as compared to the blood concentration. The aliphatic hydrocarbon levels were dependent on the amount of kerosene exposed per unit area.

The systemic distribution of kerosene components in the blood and tissues of rats following *in vitro* dermal exposures was investigated, using trimethylbenzenes and aliphatic hydrocarbons (C9-C16) as biomarkers (Tsujinoet al., 2002). The trimethylbenzenes were absorbed through the skin and detected in blood and tissues to a greater extent as compared to the aliphatics. The data indicate that kerosene components are absorbed percutaneously and distributed to the various organs via the blood circulation. Distribution of trimethylbenzenes in blood and tissues following dermal exposure is (at decreasing concentrations): kidney > blood > liver > adipose > brain > spleen > lung = muscle. Distribution of aliphatics in blood and tissues following dermal exposure is (at decreasing concentrations): blood > adipose > muscle > lung > liver > kidney > spleen > brain.

The inhalation studies demonstrate that the volatile kerosene constituents are well absorbed (31 – 54%) and are distributed mainly in the fat tissue. Aromatics were metabolised at a higher rate than naphthenes, n-alkanes, isoalkanes and 1-alkenes. Dermal application of kerosene or jet fuel generally shows that the aromatics and aliphatics are well absorbed into the skin. Subsequently, the aromatics penetrate the skin at a higher rate than the alkanes. SKINPERM calculations indicate that although skin permeation rates of alkanes, naphthenes and aromatics are more or less comparable, the latency times of alkanes are longer than the latency times of naphthenes and aromatics. After absorption, the kerosene constituents are distributed via the blood circulation to the fat tissue and various organs. Studies with oral exposure to kerosene indicate that gastrointestinal absorption of kerosene is slow and incomplete, resulting in low bioavailability.

C. Acute Toxicity

Kerosenes are of low acute toxicity, with an oral LD50 greater than 5000 mg/kg (rat), a dermal LD50 greater than 2000 mg/kg (rabbit), and an inhalation LC50 greater than 5.28 mg/L (rat). The most important effects in animals following very high oral doses were slight irritation of the stomach and the gastrointestinal tract. The only adverse effects observed in acute inhalation studies were decreased activity and breathing frequency at very high doses. Dermal application of kerosene did not lead to acute toxic systemic effects. Clinical effects observed were related to dermal irritation rather than to systemic toxicity. The acute toxicity of kerosene is not classified by EU CLP Regulation (EC No. 1272/2008).

Acute oral toxicity

In the key acute oral toxicity study (Klimisch score=1; ARCO, 1992a), groups of fasted (5 per sex), young adult, Sprague Dawley rats were given a single oral dose of undiluted thermocracked kerosene at a dose of 5000 mg/kg bw and observed for 14 days. There were no treatment related mortalities. All of the study animals exhibited one or more of the following clinical signs: nasal discharge, ocular discharge, abnormal stools, lethargy, stained coat, and alopecia. All animals gained weight during study period. At necropsy, one of the ten animals exhibited visual lesions, the remaining nine showed signs of alopecia in the inguinal and/or perineal regions. The oral LD50 was determined to be greater than 5000 mg/kg in males and females.

In supporting studies conducted on kerosene substances, rats were administered single oral gavage doses of the test substance. The results supported an oral LD50 of > 5000 mg/kg in males and females.

Acute inhalation toxicity

In the key acute inhalation toxicity study (Klimisch score = 1; API, 1987a), groups of Sprague-Dawley rats, five males and five females, were exposed by inhalation route to straight-run kerosene for 4 hours to their whole body at a single dose of 5.28 mg/L (vapour, analytical). All except one animal had normal growth rates throughout the study. The one exception on day 8 had a body weight less than its starting body weight but by the end of the study normal growth had resumed. All animals exhibited decreased activity during the exposure. Otherwise there were no treatment-related clinical signs of toxicity. No macroscopic lesions were observed in any animal at post-mortem and no microscopic changes were observed in any lung section examined. The LC50 was greater than 5.28 mg/L.

In supporting studies conducted on kerosene substances, rats were administered single doses of the test substance via inhalation. The LC50s as measured based on mortality and systemic effects do not indicate classification of kerosene as an acute inhalation toxicant. One supporting study on deodorised kerosene showed a lack of systemic effects after repeated exposure to rats (6 hours each day for 4 days) and resulted in an LC50 of > 7.5 mg/L (Carpenter et al., 1976). Another supporting study on deodorised kerosene showed a lack of systemic effects after a single 6-hour exposure to cats, and resulted in an LC50 of > 6.4 mg/L (Carpenter et al., 1976).

Acute dermal toxicity

In the key acute dermal toxicity study (Klimisch score=1; ARCO, 1992g), groups of young adult New Zealand White rabbits, five males and five females, were dermally exposed to undiluted thermocracked kerosene for 24 hours to 10% of their body surface area at a dose of 2000 mg/kg. Animals were then observed for 14 days. There were no mortalities and all animals gained weight during the study. All of the animals exhibited one or more of the following clinical signs during the observation period: dermal irritation (erythema, edema, eschar, fissuring and/or dried skin) and/or abnormal stools. Apart from skin irritation, there were no other abnormalities noted at necropsy. The dermal LD50 was determined to be greater than 2000 mg/kg in both males and females.

In supporting studies conducted on kerosene substances, rabbits were administered single dermal doses of the test substance, and results supported a dermal LD50 of > 2000 mg/kg in males and females..

D. Irritation

Skin irritation

In the key study, young adult rabbits (6 females) were dermally exposed (occlusive coverage) to 0.5 mL of undiluted kerosene/heating oil for 24 hours on both intact and abraded skin sites. Each of the test sites was evaluated for skin responses for 9 days post-exposure and was scored using the Draize scale. The mean erythema score from 24 to 72 hours was 3.46/4 while the mean edema score from 24 to 72 hours was 2.33/4. While this protocol deviates from current guidelines that state exposure should be semi-occlusive over 4 hours, and to intact skin only, this study is included as key to show the irritating nature of kerosene products.

In another guideline study conducted according to GLP and in accordance with current guidelines, young adult New Zealand White rabbits (3 per sex) were dermally exposed (semi-occlusive coverage) to 0.5 mL of undiluted odourless kerosene, for 4 hours. Animals were observed for seven days after exposure. Irritation was scored based on the Draize method (1959). The mean erythema score from 24 to 72 hours was 0.17/4 while the mean edema score from 24 to 72 hours was 0/4.

Additional supporting studies are provided on straight run kerosene, odourless kerosene, hydrocracked kerosene, hydrodesulfurised kerosene, Jet Fuel A, Jet Fuel A1, JP-5, and Cherry Point Jet Fuel A. Most of the studies are valid in their methodology, but they differ from the current OECD guidelines in that animals were exposed under occluded conditions for 24 hours instead of semi-occluded conditions for 4 hours. Considering the conditions of the test, results must be interpreted carefully for the purposes of classification and labelling. The mean scores for erythema and edema have been assessed against the deviations, and provided the test would be conducted under standard conditions, the overall weight of evidence indicates that kerosenes are irritating to skin. Kerosenes are classified as irritating to the skin according to criteria in EU CLP Regulation (EC No. 1272/2008).

Effects on skin irritation/corrosion: irritating

Eye irritation

A number of well-controlled (GLP) animal experiments performed on a variety of kerosenes indicate that none of the kerosenes and jet fuels tested were more than slightly irritating to the eyes. In addition, a number of short reports on eye irritation studies on JP-5 and JP-8 show no eye irritation whatsoever in rabbits (6 unwashed eyes; 3 washed eyes): all scores 0.0 for up to 7 days (end of the study). None of the hazard assessments of kerosene and jet fuel constituents have resulted in classification for eye irritation.

In the key study selected for primary eye irritation, 0.1mL of undiluted thermocracked kerosene was instilled into the conjunctival sac of the right eye of three female young adult New Zealand White rabbits and observed through 72 hours. Irritation was scored according to the Draize method (1959). There was no evidence of damage to the cornea or iris for all animals over all scoring periods. Mild conjunctivae indicators such as redness, chemosis, and discharge were evident at the one-hour scoring interval, but not at any of the other scoring intervals. Fluorescein staining scores were zero for all study animals over all scoring periods.

The average irritation score was 0.0 for the cornea, iris and conjunctivae.

Based on the evidence, kerosene is not an eye irritant.

E. Sensitization

In animal assays for skin sensitisation such as the Magnusson-Kligman GPMT and the Buehler assay, kerosenes and jet fuels did not trigger a positive response.

In the key dermal sensitisation study (Klimisch score=1; ARCO, 1992q), thermocracked kerosene in mineral oil was tested on male young adult Pig/Hartley guinea pigs using a modified Buehler technique. During the challenge phase, a second exposure of a 1:4 dilution of thermocracked kerosene to induced test animals did not yield higher response grades, severity, or incidence than those associated with the naive challenge control group exposed to thermocracked kerosene. During the challenge phase, exposure of 0.2% DNCB to induction positive control animals elicited significantly higher response grades, severity indices, and incidence over the naive DNCB challenge control group. The vehicle irritation control group was free of dermal irritation during the challenge phase. Therefore, under the conditions of this study, thermocracked kerosene is not considered a delayed contact sensitiser while DNCB induced an appropriate positive response.

Based on test data, there was no evidence of skin sensitisation; therefore, kerosene is not classified for skin sensitisation according to EU CLP Regulation (EC No. 1272/2008)

F. Repeated Dose Toxicity

Oral

In the key oral subchronic study (Klimisch score=1; Mattie et al., 2000), male rats were treated for 70 to 90 days with 0 (1mL of distilled water), 750, 1500, or 3000 mg/kg/day of undiluted JP-8 jet fuel, then mated to untreated females (one female at a time). Males were gavaged throughout the cohabitation period and were returned to their individual cage after successful mating. In the second part of the study, female rats were administered the test compound at doses of 0 (1mL of distilled water), 375, 750, or 1500 mg/kg/day undiluted JP-8 jet fuel for 90-day prior to mating, through mating, gestation, delivery, and lactation for a total of 21 week. During mating, they were housed with untreated males.

There were no effects on clinical signs or mortality in either sex. Haematology, clinical chemistry, and urinalysis were measured only in females without any effects noted. Body weights in male rats were decreased in a dose-dependent manner and was likely related to nephropathy, which is specific in male rats treated with hydrocarbons, and not relevant for human exposure. In females, body weight was only significantly reduced in the high-dose group. Absolute and relative liver weights were increased in mid- and high-dose females, but were not likely biologically significant due to the lack of changes in clinical chemistry or histopathology in the liver. The test compound caused perianal dermatitis (high-dose only) and stomach hyperplasia (mid- and high-dose) in the female rats. There was a dose-related decrease in pup

weight that was significant in the 750 mg/kg/day group on postnatal day 4 only and in the 1500 mg/kg/day group from postnatal day 4 through postnatal day 21 but had recovered by postnatal day 90. There were no treatment-related effects on reproduction or sperm parameters in males. There were no effects on reproduction, gestation, or litter size in females.

The study LOAEL for systemic effects is 1500 mg/kg/day and the NOAEL for systemic effects is 750 mg/kg/day, based on reduced body weight in dams and in pups. The LOAEL for adult males rats exposed to JP-8 orally was 750 mg/kg/day due to changes in clinical pathology, body weight, organ weights and the same irritation seen in female rats. The decrease in male rat bodyweight is very likely due to the male rat-specific nephropathy and is therefore not taken into account for the derivation of the oral NOAEL. The reproduction NOAEL was 3000 and 1500 mg/kg/day in males and females, respectively.

Inhalation

In a key subchronic inhalation toxicity study (Klimisch score=1; Mattie et al., 1991), JP-8 jet fuel was administered to 95 male Fisher 344 rats, 75 female Fischer 344 rats, and 100 male and female C57BL/6 mice by dynamic whole body vapour exposure at concentrations of 0, 500 or 1000 mg/m3(0, 0.5, or 1.0 mg/L) as a vapour for 24 hours per day, 7 days/week for a total of 90 days. The male rats developed hydrocarbon-induced nephropathy at both treatment concentrations. Male rats had decreased body weight and decreased absolute and relative kidney weight at both treatment concentrations. Female rats were unaffected by treatment. In mice, no significant clinical signs of toxicity were noted that differentiated the groups that were treatment-related. The NOAEC for male rats is difficult to establish, since potential adverse effects may be masked by male rat specific hydrocarbon nephropathy. However, based on the hydrocarbon-induced nephropathy and reduced body weights and increased kidney weights, the LOAEC in male rats is 500 mg/m3. The LOEC for male mice is also 500 mg/m3, but it was not treatment related. The NOAEC for female rats and mice is greater than or equal to 1000 mg/m3. This was the highest dose tested in the study.

In a subacute inhalation toxicity study (Klimisch score = 1; API, 1986), hydrodesulfurised kerosene vapour was administered to 20 Sprague-Dawley rats/sex/concentration by dynamic whole body exposure at a concentration of 24 mg/m3(0.024 mg/L) for 6 hours per day, 5 days/week for 4 weeks. There were no compound related effects in mortality, clinical signs, body weight, haematology, clinical chemistry, organ weights, or gross and histologic pathology. Therefore, the NOAEC is greater than or equal to 24 mg/m3. This was the highest dose tested in the study.

Dermal

In a key sub-chronic dermal study hydrodesulfurized kerosene was applied at concentrations of 20, 40 or 60% (v/v) at a rate of 1 ml/kg/day to the shorn intrascapular region of groups of 12 individually housed male and female, Sprague-Dawley rats (aged 7-9 weeks). This was equivalent to doses of test material of 165, 330 or 495 mg/kg/day. Dosing was continued for five days a week for 13 weeks. In addition a group of 12 male and 12 female rats of similar age were administered mineral oil at a dose rate of 1 ml/kg/day; these animals served as vehicle controls. 12 rats/sex/group each in the vehicle controls and high dose group were maintained for a 4-week recovery period. Ingestion of the test material was prevented by using a collar and removal of any residual test or control material from the skin. Animals were observed for clinical signs prior to dosing and 1, 6 and 24 hours after the first dose. Subsequently, observations were made prior to each dose being applied.

Prior to the administration of each dose, the treated skin site was evaluated for dermal irritation using the Draize scoring method. Body weights were recorded prior to the first dose and weekly thereafter. An ophthalmic examination was conducted on each rat prior to application of the first dose and again prior to sacrifice at the end of the study. During the week prior to the first dose, each rat was subjected to a functional observation battery (FOB). The FOB was conducted again 1, 6 and 24 hours after the first dose and at 7 and 14 days. During the study, the FOB, motor activity and startle response testing was conducted on all rats at weeks 4, 8 and 12. At week 14 blood samples were collected from 12 animals/sex/group. Full necropsies were performed at week 14 on 6 rats/sex/group and at week 18 on the recovery rats (vehicle and high dose groups). Each full necropsy included an examination of the external surface of the body and its contents. The remaining six rats of each group were anesthetized with an intraperitoneal injection of Pentothal and transcardially perfused in-situ using 10% neutral-buffered formalin and given a limited necropsy. For these rats, no organs were weighed and specific tissues were also collected for subsequent microscopic testing.

There was a generally dose-related increase in the incidence and severity of various skin conditions at the treated site. Males seemed to be more sensitive than females as they were affected at all doses, however, the effects indicated very little irritation. Recovery group animals revealed complete recovery in the females and minimal hyperkeratosis in the high dose group males. At necropsy no substance-related observations were made for males in any group. In the females there was a suggestion of a possible treatment-related effect which occurred in 7 rats across all groups and consisted of skin crusts or ulceration at the site of application of test material. Haematological and serum clinical parameters were unaffected by treatment.

All animals survived until scheduled termination. There were no test substance-related effects on survival, clinical observations (apart from skin irritation), neurobehavioral signs or ophthalmological findings. The NOEL for systemic toxicity was >495 mg/kg/day. The LOEL for slight dermal irritation was 165 mg/kg/day, equivalent to ~ 1mg/cm2.

G. Genotoxicity

In vitro gene mutation in mammalian cells

Key in vitro gene mutation studies in mammalian cells were identified. In a study by the American Petroleum Institute (API, 1984b), cultures of mouse lymphoma cells were exposed to hydrodesulfurised kerosene with or without metabolic activation by Aroclor 1254-induced rat liver S9 fraction. Under non-activation conditions the test material induced a good range of toxicities for evaluation (relative growths ranged from 2.8% to 65.3%). None of the assays induced a mutant frequency that exceeded the minimum criterion (40.8 x 10-6). The test material was not mutagenic under non-activation conditions. In the presence of metabolic activation a wide range of toxicities was induced (6.1 to 107.9% relative growths). The minimum criterion mutant frequency of 69.0 x 10-6 was not exceeded. The test material was therefore considered non mutagenic under activation conditions. In a study by API (1977) (Klimisch score = 1), mouse lymphoma L5178Y cells were exposed to straight-run kerosene in acetone vehicle at concentrations ranging from 0.04 to 0.065 µL/mL (with metabolic activation) or 0.006 to 0.13 µL/mL (without activation). There was no evidence that straight-run kerosene induced mutant colonies over background levels.

In vitro cytogenicity in mammalian cells

Hydrodesulfurised kerosene was tested in the sister chromatid exchange assay using Chinese hamster ovary cells (API, 1988a). The assay was conducted with Aroclor-induced rat liver S-9 activation system. A small but statistically significant increase in the frequency of sister chromatid exchanges was observed at the high and low concentrations with metabolic activation. These increases appeared to be random and of no biological significance. There were no significant increases observed at any concentration in the absence of metabolic activation. Under the conditions of the study, hydrodesulfurised kerosene is considered to be negative in the sister chromatid exchange assay with Chinese hamster ovary cells.

In vivo cytogenicity

Based on weight of evidence kerosene substances were found to be non-mutagenic through cytogenic investigations.

In six in vivo bone marrow cytogenetic studies in the rat, there were no indications of chromosomal aberrations. Although an in vivo Sister Chromatid Exchange study in the mouse gave positive findings in the male group (but not in the females) the positive findings in the males were associated with signs of toxicity (lethargy and weight loss) at the very high top dose used in the study (4000mg/kg), both on the day of the administration of the kerosene and the day after (when they were sacrificed).

In a rat bone marrow micronucleus assay (API, 1985c, Klimisch score = 1), straight run kerosene (CAS# 800-20-6) was administered to Sprague Dawley rats. Straight run kerosene was not considered to induce chromosomal aberrations in bone marrow cells of rats. In another bone marrow micronucleus assay (API, 1984b, Klimisch score = 1), hydrodesulfurised kerosene (CAS# 64742-81-0) was administered to rats. No clinical signs of toxicity were exhibited by the rats, and there was no significant increase in frequency of micronucleated polychromatic erythrocytes in bone marrow as compared to control. In a study by API (1977) (Klimisch score = 1), straight-run kerosene (CAS# 8008-20-6) was administered to 45 male rats. No significant increase in the frequency of micronucleated polychromatic erythrocytes was observed.

In vivo gene mutation

Key in vivo gene mutation studies were identified. In a sperm cell dominant lethal mutation assay (API, 1980b, Klimisch score = 1), Jet Fuel A was administered via inhalation route to male mice at concentrations of 100 or 400 ppm for a 6-hour exposure period, 5 days per week for 8 weeks. Males were mated with females, and the uteri of pregnant females were examined for living and dead implants. Jet Fuel A did not increase the incidence of post-implantation deaths. In another study by API (1973) (Klimisch score = 1), deodorised kerosene was administered subcutaneously to 10 male Swiss-Webster mice in corn oil vehicle or intraperitoneally to 10 Long-Evans rats undiluted at a dose of 1.0 mL/kg. Males were mated with females, and no pattern of decreased pregnancy rate or increased embryo loss was observed in the females.

H. Carcinogenicity

No studies are available.

I. Reproductive Toxicity

There are no specific reproductive toxicity data for the substance but there are data available with ECHA as migrated information which is read-across based on grouping of substances (category approach).

An OECD Guideline 415 One-Generation Reproduction Toxicity study was conducted.
This was a reproductive study performed in two parts. In the first part, males were treated for 70 to 90 days with 0 (1mL of distilled water), 750, 1500, or 3000 mg/kg/day of undiluted JP-8 jet fuel, then mated to untreated females (one female at a time). In the second part of the study, female rats were administered the test compound at doses of 0 (1mL of distilled water), 375, 750, or 1500 mg/kg/day undiluted JP-8 jet fuel for 90 -day prior to mating, through mating, gestation, delivery, and lactation for a total of 21 weeks.

There were no changes in clinical signs or mortality in parental animals. Body weights in male rats were decreased in a dose-dependent manner. Terminal body weights were approximately 545 grams, 520 grams, 475 grams, and 315 grams in the control, 750, 1500, and 3000 mg/kg/day, respectively. In females, body weight was only significantly reduced in the high-dose group, but the differences were not significant at terminal sacrifice. The body weight in females at 20 weeks (1 week before sacrifice) was approximately 400 grams, 385 grams, 382 grams, and 335 grams in the control, 375, 750, and 1500 mg/kg/day, respectively. Haematology was not measured in the males and no effects were noted in the females. Clinical chemistry was not measured in the males and no effects were noted in the females. Urinalysis was not measured in the males and no effects were noted in the females. Absolute and relative liver weights were increased in mid- and high-dose females, but were not accompanied by any histological findings. The test compound caused perianal dermatitis (high-dose only) and stomach hyperplasia (mid- and high-dose) in the female rats.

There were no treatment-related effects on reproduction or sperm parameters in males. There were no effects on reproduction, gestation, or litter size in females.

The lowest NOAEL based on parental body weight was determined to be 750 mg/kg/day.

The F1 generation was not examined for clinical signs though no mention would suggest no significant signs were noted. No mortality was observed. There were no effects on offspring viability. However, there was a dose-related decrease in pup weight that was significant in the 750 mg/kg/day group on postnatal day 4 only and in the 1500 mg/kg/day group from postnatal day 4 through postnatal day 21. The 1500 mg/kg/day group recovered by postnatal day 90.

The NOAEL based on offspring body weight was determined to be 750 mg/kg/day.

J. Developmental Toxicity

In a developmental toxicity study, undiluted JP-8 jet fuel was administered to 30 Sprague-Dawley (Crl:CD) rats/dose by gavage at various volumes to achieve dose levels of 0 (sterile water), 500, 1000, 1500, or 2000 mg/kg bw/day from days 6 through 15 of gestation.

There was a significant decrease in maternal weight gain with doses of 1000 mg/kg/day or greater. Maternal necropsy weight was significantly different than the control in the 1500 and 2000 mg/kg/day groups. There were no apparent clinical signs of toxicity. Reproductive endpoints were not assessed in this study because females were pregnant prior to treatment and did not deliver, so only developmental endpoints can be assessed. Thirteen females (one 1000 mg/kg/day; three 1500 mg/kg/day, and nine 2000 mg/kg/day) were found dead. Although there appears to be a dose-dependent increase in the mortality, necropsy found the cause of death to be related to the presence of the test compound in the lungs indicating dosing into the lungs instead of the gastrointestinal tract. The maternal LOAEL is 1000 mg/kg/day, based on reduced body weight gain. The maternal NOAEL is 500 mg/kg/day.

There was a significant decrease in fetal weight in both male and female fetuses dosed with 1500 and 2000 mg/kg/day. The test compound did not significantly increase the incidence of malformations or variations compared to the control nor was the sex ratio altered. The developmental LOAEL is 1500 mg/kg/day, based on reduced fetal weight. The developmental NOAEL is 1000 mg/kg/day. It can be concluded that the test substance is not toxic to development.

This study received a Klimisch score of 1 and is classified as reliable without restrictions because it was carried out in a method equivalent/similar to OECD TG 414.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for the substance follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The NOAEL for reduced maternal body weight is 500 mg/kg/day, based on reduced body weight in dams and in pups treated under a repeat dose regimen. . The NOAEL from this study will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10

UF_D (database uncertainty) = 1

Oral RfD = 500 /(10 x 10 x 1 x 10 x 1) = 500/1,000 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.500 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

There are no carcinogenicity studies on the substance or related hydrocarbons. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

The substance does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidizing potential

The substance is classified as a "Flammable Liquid Category 3"

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is of low acute concern to aquatic organisms..

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies on hydrotreated light petroleum distillate surrogates.

Table 2: Acute Aquatic Toxicity Studies on hydrotreated light petroleum distillate surrogates

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LL_{50}	2-5	1	ECHA
Daphnia magna	48-h EL_{50}	1.4	1	ECHA
Raphidocelis subcapitata	72-h EC_{50}	<1-3 (average of 2)	1	ECHA
Selenastrum capricornutum	72-h EC50	3.7	2	ECHA

Chronic Studies

There are no long-term toxicity studies on fish. A single long term study on invertebrates is discussed below.

In a 21-day semi-static chronic reproductive toxicity test (OECD 211; KS = 1) on *Daphnia magna*, hydrodesulfurised kerosene was evaluated using water accommodated fraction methodology. The actual loading rates were 0 (control), 0.08, 0.19, 0.48, 1.2, and 3.0 mg/L. Under the conditions of this test, the 21-day chronic reproductive NOEL for kerosene is 0.48 mg/L. The LOEL is 1.2 mg/L. The EL50 based on reproduction is 0.89 mg/L (echa).

C. Terrestrial Toxicity

There are no terrestrial toxicity studies for this substance.

D. Calculation of PNEC

The PNEC calculations for hydrotreated light petroleum distillate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available from acute tests on three trophic levels. There is one long term study on a single trophic level organism, *D. magna*.

On the basis that the data consists of short-term studies from three trophic levels and a long-term study from one trophic level, an assessment factor of 100 is applied to the 21-day chronic reproductive NOEL for kerosene of 0.48 mg/L. The $PNEC_{aquatic}$ is 0.005 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 1.5E05 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
= (1.9E08/1280) x 1000 x 0.001
= 1.48E05

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
= 0.8 + [0.2 x 4E08/1000 x 2400]
= 1.9E08

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
= 1E10x 0.04
= 4E08

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for fatty acids, C8-C16, 2-ethylhexyl esters calculated from EPISUITE™ using the MCI is 79,726 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

<u>PNEC soil</u>
There are no experimental toxicity testing results available for the substance or its noted surrogates. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The PNECsoil is 6.7E05 mg/kg soil dry weight.

The calculations are as follows:

PNECsoil = (Kpsoil/BDsoil) x 1000 x PNECwater
= (2E08/1500) x 1000 x 0.005
= 6.7E05
Where:
Kpsoil = soil-water partition coefficient (m3/m3)
BDsoil = bulk density of soil (kg/m3) = 1,500 [default]

Kpsoil = Koc x foc
= 1E10 x 0.02
= 2E08

Where:
Koc = organic carbon normalised distribution coefficient (L/kg). The Koc for the substance is 1E10 .

Foc = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

The substance or similar compounds are readily biodegradable; thus they do not meet the screening criteria for persistence.

Based on the estimated BCF values, derived from EPISUITE estimates (BCF = 3.162 L/kg wet-wt) the substance the substance does not meet the screening criteria for bioaccumulation.

The NOEC values from acute and chronic aquatic toxicity studies on the substance indicate it does not meet the screening criteria for toxicity.

Therefore, hydrotreated light petroleum distillates are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Asp. Tox. 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

<u>Skin Contact</u>
Wash with soap and water. Get medical attention if symptoms occur.

<u>Inhalation</u>

Treat symptomatically. Move to fresh air. Get medical attention if symptoms persist.

Ingestion
In case of ingestion, always assume that aspiration has occurred. Do not induce vomiting. Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Foam (Specifically trained personnel only)- Water fog (Specifically trained personnel only)- Dry chemical powder- Carbon dioxide- Other inert gases (subject to regulations)- Sand or earth
Specific Exposure Hazards
None known.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment.

Environmental Precautions
Do not release to open drains or surface water. Not regarded as dangerous to the environment.

Steps to be Taken if Material is Released or Spilled
Collect free product with suitable means. Transfer collected product and other contaminated materials to suitable containers for recycle, recovery or safe disposal. Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
Ensure that all relevant regulations regarding explosive atmospheres, and handling and storage facilities of flammable products, are followed.

Other Handling Precautions
Wash hands thoroughly after handling.

Storage
Keep containers tightly closed and properly labelled. Protect from the sunlight5.3. Light hydrocarbon vapours can build up in the headspace of containers. These can cause flammability / explosion hazard

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for the substance.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Minimize skin contact.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Minimize eye contact.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

The substance retains UN 1223 transport code is listed as such within the Australian Dangerous Goods (AUS 2018)

is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.AUS (2018). Australian Code for the Transport of Dangerous Goods by Road & Rail Edition 7.6, 2018. Commonwealth of Australia National Transport Commission, Level 3, 600 Bourke Street MELBOURNE, VIC, 3000.

BASF (2012). GPS Safety Summary: Fatty acids, C8-C16, 2-ethylhexyl ester. Available at: http://www.safety-summaries.basf.com/group/corporate/safety-summaries/en/literature-document:/GPS+Safety+Summaries--Fatty+acids+C8+16+2+ethylhexyl+ester-English.pdf.

Bookstaff, R.C., Stuard, S.B., Ward, S.R., Pesik, P.K., and Henwood, S.M. (2004). The safety of ethyl oleate is supported by a 91-day feeding study in rats. Regul. Toxicol. Pharmacol. 39: 202-213.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

HYDROXYPROPYL GUAR

This dossier on hydroxylpropyl guar presents the most critical studies pertinent to the risk assessment of hydroxypropyl guar in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Hydroxylpropyl Guar

CAS RN: 39421-75-5

Molecular weight: 200,000 to 300,000 daltons (Glickman, 1969)

Hydroxypropyl guar a propylene glycol ether derivative of guar gum. Guar gum is a resinous material derived from milled endosperm from guar beans of the legume *Cyamopsis tetragonolobus*. Structurally, it is a galactomannan (high molecular weight carbohydrate polymer) consisting of a main chain of D-mannose with a side chain of D-galactose at approximately every second mannose unit. The mannose units are β-(l-4) linked, and the single D-galactose units are joined to the main chain by α-(1-6) linkages.

SYNONYMS: Hydroxypropyl guar; hydroxypropyl guar gum; guar gum, 2-hydroxypropyl ether

II. PHYSICAL AND CHEMICAL PROPERTIES

Hydroxypropyl guar is a white to yellow fine powder that is very slightly soluble in water (Johnson et al., 2015).

III. ENVIRONMENTAL FATE PROPERTIES

No biodegradation studies are available on hydroxypropyl gum. Hydroxypropyl guar is the propylene glycol derivative of a carbohydrate polymer consisting of D-mannose and D-galactose sugars from the guar bean. It is expected to be readily biodegradable.

Hydroxypropyl guar is not expected to bioaccumulate based on its large molecular weight.

IV. HUMAN HEALTH HAZARD ASSESSMENT

As the propylene glycol derivative of guar gum, hydroxypropyl guar would be expected to have similar toxicological properties to guar gum. Thus, the toxicity data on guar gum have been used to read-across to hydroxypropyl guar.

A. Summary

There are no mammalian toxicity data available on hydroxypropyl guar, except for one *in vitro* genotoxicity study; thus data on guar gum have been used to read-across to hydroxypropyl guar. Guar gum is exhibits very low acute toxicity by the oral route. It is non-irritating to the skin and minimally irritating to the eyes. Repeated dose toxicity studies showed minimal toxicity in dietary studies. Unlike guar gum, hydroxylpropyl guar was mutagenic in an Ames test in the presence, but not absence, of metabolic activation. Oral exposure to guar gum did not affect fertility in rats; nor was there any indication of developmental toxicity in rats or mice.

B. Acute Toxicity

There are no acute toxicity studies available for hydroxypropyl guar. The oral LD_{50} for guar gum in rats was reported to be 7,060 mg/kg (Graham et al., 1981). [Kl. score = 2]

C. Irritation

There are no irritation studies available for hydroxypropyl guar. Guar gum is non-irritating to the skin, and minimally irritating to the eyes (McCarty *et al.*, 1990).

D. Sensitization

There are no animal sensitization studies available for either hydroxypropyl guar or guar gum. However, under REACH, some data submitters indicate they consider this substance a respiratory sensitizer.

E. Repeated Dose Toxicity

Oral

There are no repeated dose toxicity studies available for hydroxypropyl guar.

Male and female Osborne-Mendel rats were given diets containing 0, 1, 2, 4, 7.5, or 15% guar gum for 91 days. The average daily intakes are: 0, 580, 1,187, 2,375, 4,561, and 10,301 mg/kg-day for males; and 0, 691, 1,362, 2,762, 5,770, and 13,433 mg/kg-day for females. There were no deaths during the study. Body weights were significantly decreased in the ≥1% females and the ≥7.5% males. Liver weights were decreased in the ≥1% dietary groups. Kidney weights were decreased in the ≥7.5% dietary groups

and were borderline significant in the 4% group. The 15% males had reduced bone marrow cellularity; although the level was within normal limits, several of the rats were at the lower end of the normal range. The LOAEL for this study is 691 mg/kg-day based on reduced body weights in the female rats (Graham et al., 1981). [Kl. score = 2]

Male and female F344 rats and B6C3F$_1$ mice were given diets containing 0, 6,300, 12,500, 25,000, 50,000 or 100,000 ppm guar gum for 13 weeks. Mean body weights were decreased in the 100,000 ppm male rats and in the ≥50,000 ppm female mice. A dose-related decrease in feed consumption was observed for male and female rats; male and female mice were comparable or higher than that of controls. There were no compound-related clinical signs or histopathological effects. The NOAELs for this study is 50,000 and 25,000 ppm for rats and mice, respectively. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; U.S. EPA), the NOAELs corresponds to 2,500 mg/kg-day for rats and 3,250 mg/kg-day for mice (NTP, 1982). [Kl. score = 2]

Male and female F344 rats and B6C3F$_1$ mice were given diets containing 0, 25,000 ppm or 50,000 ppm guar gum for 103 weeks. Mean body weights of the high-dose females were lower than those of the controls after week 20 for mice and week 40 for rats. No compound-related clinical signs or adverse effects on survival were observed. Feed consumption by dosed rats and mice of either sex was lower than that of controls. There were no non-neoplastic histopathological effects in either rats or mice that were treatment-related. The NOAEL for both rats and mice is 25,000 ppm. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; U.S. EPA), the NOAELs corresponds to 1,250 mg/kg-day for rats and 3,250 mg/kg-day for mice (NTP, 1982). [Kl. score = 2]

Inhalation
No studies are available.

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

Hydroxypropyl guar was not mutagenic to *S. typhiumurium* strains TA 98, TA 100, TA 1535, TA 1537, and TA 1538 in the absence of metabolic activation. In the presence of metabolic activation hydroxypropyl guar was mutagenic to S. typhimurium strains TA 98, TA 100, TA 1537, and TA 1538, but not to TA 1535 (Johnson et al., 2015).

In Vivo Studies

There are no studies available for hydroxypropyl guar.

G. Carcinogenicity

There are no studies available for hydroxypropyl guar.

H. Reproductive Toxicity

Oral
There are no studies available for hydroxypropyl guar.

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intake for the female rats during gestation were 0, 700, 1,400, 2,700, 5,200, or 11,800 mg/kg-day. Fertility was unaffected by treatment. There were slightly fewer corpora lutea and implantations in the 15% dietary group, but implantation efficiency was unaffected. The NOAEL for reproductive toxicity is 5,200 mg/kg-day (Collins et al., 1987). [Kl. score = 2]

I. Developmental Toxicity

Oral
There are no studies available for hydroxypropyl guar.

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intake for the female rats during gestation were 0, 700, 1,400, 2,700, 5,200, or 11,800 mg/kg-day. There were no deaths during the study. In the 15% group, the number of viable fetuses per litter were slightly reduced, but was not statistically significantly different from controls. The authors indicate that the reduction may have been an effect of the decreased number of corpora lutea because the number of resorptions was unaffected in this treatment group. There was no treatment-related effect on fetal development or sex distribution, and there was no teratogenic effects (Collins *et al.*, 1987). [Kl. score = 2]

Pregnant female rats were dosed by oral gavage with 0, 9, 42, 200, or 900 mg/kg guar gum on GD 6 to 15. There was no maternal or developmental toxicity at any dose level. The NOAEL for maternal and developmental toxicity is 900 mg/kg-day (FDRL, 1973). [Kl. score = 2]

Pregnant female CD-1 mice were dosed by oral gavage with 0, 8, 37, 170, or 800 mg/kg guar gum on GD 6 to 15. A significant number of deaths (6 out of 29) occurred in the 800 mg/kg dose group. There was indications of maternal toxicity in the surviving high-dose dams. There was no developmental toxicity at any dose level. The NOAELs for

maternal and developmental toxicity is 170 and 800 mg/kg-day, respectively (FDRL, 1973). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for guar gum follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

In a two-year NTP chronic bioassay, female rats and mice given 50,000 ppm guar gum in their feed had lower body weights. There were no treatment-related nonneoplastic lesions observed in either rats or mice. The NOAEL for this study is 25,000 ppm for rats and mice, which corresponds to 1,250 mg/kg-day for rats and 3,250 mg/kg-day for mice.

The NOAEL of 1,250 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 1,250/(10 x 10 x 1 x 1 x 1) = 1,250/100 = 13 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (13 x 70 x 0.1)/2 = 46 mg/L

B. Cancer

There are no carcinogenicity studies on hydroxypropyl guar. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Hydroxypropyl guar does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

No studies are available on the aquatic or terrestrial toxicity of hydroxypropyl guar. As the hydroxypropyl derivative of guar gum, it would be expected to have similar properties to a non-ionic polymer and exhibit low to potentially moderate acute toxicity to aquatic organisms.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Hydroxypropyl guar is a derivative of a naturally occurring polysaccharide from the guar plant or cluster bean; it expected to be readily biodegradable. Thus, it is not expected to meet the screening criteria for persistence.

The molecular weight of hydroxypropyl guar ranges from 200,000 to 300,000 daltons. Thus, guar gum is not expected to meet the criteria for bioaccumulation.

No aquatic toxicity data are available on hydroxypropyl guar. It is not possible to determine whether hydroxypropyl guar meets the toxicity criteria.

The overall conclusion is that hydroxypropyl guar is unlikely to be a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Serious health hazard

B. Labelling

Danger!
According to the classification provided by companies to ECHA in CLP notifications this substance may cause allergy or asthma symptoms or breathing difficulties if inhaled. Some data submitters indicate they consider this substance a respiratory sensitizer.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact
Remove contaminated clothing. Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

Notes to Physician
May cause asthma-like (reactive airways) symptoms.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus for fire fighting.

C. Accidental Release Measures

Personal Precautions
Avoid dust formation.

Environmental Precautions
No special environmental precautions required.

Steps to be Taken if Material is Released or Spilled
Sweep up and dispose in suitable, closed containers.

D. Storage And Handling

General Handling
Avoid creating or inhaling dust.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard specifically for hydroxypropyl guar.

Engineering Controls
Ensure adequate ventilation.

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Handle with gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Hydroxypropyl guar is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Bailey, D., and Morgareidge, K. (1976). Comparative acute oral toxicity of 12 food grade gums in the mouse, rat, hamster, and rabbit. Food and Drug Research Labs Papers No., 124; cited in NTP (1982).

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Glicksman M. (1969). Gum technology in the Food Industry, pp. 590, Academic Press, New York; cited in Yoon *et al.* (1998).

International Research and Development Corp (1988). Teratology Study of Guar Gum in Rabbits. TSCATS database, EPA Doc. No. 88-920004924, Fiche No. OTS0542101; cited in NZ HSNO CCID. http://www.epa.govt.nz/search-databases/Pages/ccid-details.aspx?SubstanceID=1930.

Johnson, W., Jr., Heldreth, B., Bergfeld, W.F., Belsito, D.V., Hill, R.A., Klaassen, C.D., Liebler, D.C., Marks, J.G., Jr., Shank, R.C., Slaga, T.J., Snyder, P.W., and Andersen, F.A. (2015). Safety assessment of galactomannans as used in cosmetics. Int. J. Toxicol. 34(Suppl. 1): 35S-65S.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Maio, J.L., Cartier, A., L'Archevêque, J., Ghezzo, H., Soucy, F., Somers, J., and Dolovich, J. (1990). Prevalence of occupational asthma and immunologic sensitization to guar gum among employees at a carpet-manufacturing plant. J. Allergy Clin. Immunol. 86: 562-569.

NTP (1982). NTP Technical Report on the Carcinogenesis Bioassay of Guar Gum (CAS No. 9000-30-0) in F344 Rats and B6C3F_1 Mice (Feed Study), National Toxicology Program, Research Triangle Park, NC.

Yoon, S.-J., Chu, D.-C., and Juneja, L.R. (2008) Chemical and physical properties, safety and application of partially hydrolyzed guar gum as dietary fiber. J. Clin. Biochem. Nutr. 42: 1-7.

IRON GLUCONATE

This dossier on iron gluconate presents the most critical studies pertinent to the risk assessment of iron gluconate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC):

CAS RN: 299-29-6

Molecular formula: $C12H22FeO14 \cdot 2H2O$

Molecular weight: 446.14 g/mol

Synonyms: Iron gluconate; iron digluconate;

SMILES: C(C(C(C(C(C(=O)[O-])O)O)O)O)O.C(C(C(C(C(C(=O)[O-])O)O)O)O)O.[Fe+2]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Iron Gluconate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Light yellow-green solid with a mild burnt sugar.	2	ECHA
Melting point	>120°C (decomposition)	1	ECHA
Density	0.79 g/cm^3 @ 20°C	1	ECHA
Vapor pressure	586.5 Pa @ 25°C	1	ECHA
Partition coefficient (log K_{ow})	-7.7 (QSAR)	2	EPA, 2019
Water solubility	118 g/L @ 25°C	1	ECHA
Auto flammability	No self-ignition was observed.	1	ECHA

Iron gluconate dissociates in aqueous media to

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Iron gluconate is expected to biodegrade readily, and has low potential to bioaccumulate.

B. Biodegradation

No biodegradation studies are available on iron gluconate involving freshwater organisms.

In an OECD 306 test involving seawater, degradation of iron gluconate after 28 days was 79% and 78% at concentrations of 6.0 and 7.5 mg/L, respectively. Iron gluconate was considered ready biodegradability but failed the 10-day window (ECHA) [Kl. score = 2].

In a Ready Biodegradability Closed Bottle test (EU Method C.4-E), degradation of sodium gluconate (CAS No. 527-07-1) was 67% after 3 days, indicating ready biodegradability (ECHA) [Kl. score =2].

In an OECD 302 B inherent biodegradability Zahn-Wellens/EMPA test, degradation of sodium gluconate (CAS No. 527-07-1) was 98.9% after 3 days (ECHA) [Kl. score = 2].

Using BIOWIN v4.10 in in EPISUITE™ (EPA, 2019), iron gluconate is expected to be readily biodegradable.

Based on the results of the above studies, iron gluconate is expected to be readily biodegradable.

C. Environmental Distribution

<u>Adsorption/desorption</u>
No experimental data are available for iron gluconate. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from the molecular connectivity index (MCI) is 18.4 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on iron gluconate. Using BCFBAF v3.01 in EPISUITE™ (EPA, 2019), an estimated BCF value of 3.162 L/kg was determined for iron gluconate, indicating that it has a low potential for bioaccumulation.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Based on the available data, iron gluconate is not toxic via the oral or dermal exposure routes, and no data exists to evaluate the inhalation risks. Iron Gluconate did not contain any structural alerts for skin or eye irritation. The lack of alerts and the physical-chemical properties indicate that iron gluconate should not be reactive to the skin or the eye. There are no skin sensitisation studies on ferrous gluconate. Results of a study conducted with a structurally similar compound, D-gluconic acid found no sensitization. There is no information on repeated dose toxicity on iron gluconate, but one read-across study, a 28-day repeated dose toxicity study (KL = 1), is available for the oral route of exposure that reported reliable no-effect levels on repeated dose toxicity and reproductive and developmental endpoints. No effect levels for repeated dose toxicity were found at 125 mg/kg-bw, and at 500 mg/kg-bw for reproductive and developmental endpoints. Iron gluconate was deemed not genotoxic by read-across in one study.

B. Acute Toxicity

Based on the available data, iron gluconate is not toxic via the oral or dermal exposure routes, and no data exists to evaluate the inhalation risks.

The acute oral toxicity of iron gluconate was assessed in one study (Kl = 2) with Sprague-Dawley rats; the LD50 was 2237 mg/lg. At doses higher or equal to the LD50, stomach and small intestine were dilated and filled with dark fluid and occasionally blood. Stomach and small intestine mucosa were covered with grey-green granular material. Caecum and large intestine contained black liquid feces. At sub-lethal doses, occasional dilation of upper gastrointestinal tract with fluid. Small hemorrhages were seen in stomach or small intestine. Black liquid farces was reported. A read-across study tested D-gluconic acid in Sprague-Dawley rats (Kl = 2) found a LD50 of greater than 2,000 mg/kg bw via the dermal exposure route.

C. Irritation

Iron Gluconate did not contain any structural alerts for skin or eye irritation. The lack of alerts and the physical-chemical properties indicate that iron gluconate should not be reactive to the skin or the eye.

Iron Gluconate, which can be read across to D-Gluconic acid due to the comparable structures and relevant properties has been tested for skin and eye irritation. Gluconic Acid was applied three times successively at a duration of three minutes, one hour, and four hours, respectively (exposure of one animal) to the skin of New Zealand white rabbits. No dermal response to treatment was observed in any animals throughout the

observation period. One dose consisting of 0.1 mL was applied to the eyes of rabbits with the eyelids held closed for one second to prevent loss of dose. Ocular changes were assessed and recorded immediately, one hour after treatment, 24 hours, 48 and 72 hours after treatment. did not induce colouration of the eye and did not interfere with grading of lesions (Kl = 2). 24 hours after instillation, one animal had severe chemosis with lacrimation and severe redness of the conjunctivae, lesions of iris and cornea on an area greater than one quarter. 72 hours after instillation, only slight chemosis and slight redness of the conjunctivae persisted. No ocular lesion persisted in any animal at the end of the exposure period.

D. Sensitization

There are no skin sensitisation studies on ferrous gluconate. Results of a study conducted with a structurally similar compound, D-gluconic acid, are reported and used for read across (Kl = 2). Groups of four mice were treated with the undiluted test material or the test material at concentrations of 50% or 25% v/v in dimethyl formamide; no sensitization was noted. Based on this result, D-Gluconic Acid is not sensitising. Via read across iron gluconate is not classified as a sensitiser.

E. Repeated Dose Toxicity

There is no information on repeated dose toxicity on iron gluconate, but one read-across study is available for the oral route of exposure that reported reliable no-effect levels; there are no other studies available for the other exposure routes on REACH.

A 28-day repeated dose toxicity study (KL = 1) tested a read-across substance iron dichloride (CAS No.7758-94-3) (NIER, 2004). Male and female SD rats were dosed with the test substance (0 (Control group), 125, 250 and 500 mg/kg/day) from two weeks before mating. Male SD rates were dosed once a day till two weeks after mating while female SD rats were dosed once a day up to postpartum day 4. A total of 42 doses were provided for male rats while female rates had 42 to 54 dosages depending on mating and delivery of individuals. Clinical signs and mortality were observed and body weight and food and water consumption were measured. In the necropsy, gross examination of organs and tests on corpus luteum graviditatis and implantation rates were conducted. In addition, tests for sensory and motor functions, urinalysis and hematological and blood chemical tests were given and organ weights were measured for five individuals randomly selected from each group. External abnormalities, sex ratio, body weights, CRL (Crown Rump Length) and survival rate were observed on postpartum days 0 and 4.

During the observation period, the main group dosed with the substance showed signs such as melaena (black stool) and salivation but these signs were observed to disappear after dosing in the recovery group. There was no mortality in male SD rats, but three mortalities took place in female individuals at 500 mg/kg. The cause for mortalities was presumably the gastrointestinal damage by the substance. It was found that male

individuals were more sensitive to body weight and food consumption than female counterparts. The change by the test substance was not recognized in mating data, sensory functions, motor functions, urine analysis and blood test. Gastric hemorrhage with blackened liver and black pigmentation of liver discovered in the necropsy findings was presumed to be caused by the test substance, but it was found to improve for the recovery period of two weeks. Weight changes in the liver and adrenal were observed in the absolute and relative organ weights of male individuals at 250 and 500 mg/kg and female individuals at 500 mg/kg. The histopathological test found parenchymal hemosiderosis and hyperplasia of adrenocortical zona fasciculate as well. It was found that the substance had no effect on birth rate, survival rate, body weight and CRL of neonates. As a result of the test, the NOAEL of repeated doses to male and female SD rats were 125 and 250 mg/kg/day, respectively.

F. Genotoxicity

There are few studies for this endpoint on ferrous gluconate. In a bacterial reverse mutation assay (Kl = 2), S. typhimurium TA 1535, 1537, 1538 glucono-delta-lactone was negative both with and without metabolic activation. However, some of the positive controls did not appear to be valid. In a mammalian germ cell study (Kl = 4) (Drosophila SLRL assay), iron gluconate did not contain any structural alerts for mutagenicity. The lack of alert and the physical-chemical properties indicate that iron gluconate should not be reactive to DNA.

From this read across ferrous gluconate is classified as non-hazardous for this endpoint.

G. Reproductive and Developmental Toxicity

There are no toxicity to reproduction studies on iron gluconate. Results of a studies conducted with a structurally similar compounds: Iron Sucrose, Ferric Carboxymaltose and iron (II) chloride are reported and used for read across.

Iron (II) Chloride is a good read across material for evaluating the reproductive toxicity potential of iron gluconate because of similarities in their phys/chem properties and similar systemic exposures absorption, distribution, and elimination properties by the oral route of administration. Via read across Iron Gluconate is not classified as toxic to reproduction.

A 28-day repeated dose toxicity study (KL = 1) tested a read-across substance iron dichloride (CAS No.7758-94-3) with Sprague-Dawley rats (NIER, 2004). No treatment-related effects were observed on mean live neonates, birth rates, survival rates and sex ratios on days 0 and 4 post-partum. The only abnormalilty found in the external appearance examinations is an acaudate was observed in one neonate at 500 mg/kg. Crown Rump Length (CRL) of female neonates showed a significant decrease at 125 mg/kg on Day 4 post-partum. There were no treatment-related effects on reproductive

functions in parental animals and development of neonates at any doses tested. The NOAEL for reproduction and developmental toxicity was considered to be 500 mg/kg/day.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for iron gluconate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The lowest NOAEL from these studies is 125 mg/kg-day based on a 28-day repeated dose toxicity study (KL = 1) based on no difference in organ weights, which were observed at higher doses (NIER, 2004). The NOAEL of 125 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 125/(10 x 10 x 1 x 10 x 1) = 125/1000 = 0.1 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)

Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.1 x 70 x 0.1)/2 = 0. 4 mg/L

B. Cancer

Iron gluconate is not a carcinogen, so no cancer reference value or drinking water guideline was developed for carcinogenic endpoints.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Iron gluconate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance demonstrates a relatively low level of acute aquatic toxicity. Data from specific tests are shown below.

B. Aquatic Toxicity

Acute Studies

There are no aquatic toxicity studies on iron gluconate using freshwater species. Table 2 lists the results of acute aquatic toxicity studies on iron gluconate using marine species.

Table 2: Acute Aquatic Toxicity Studies on Iron Gluconate (Seawater Species)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Scophthalmus mamimus	96-hr LC_{50}	>1,000	1	ECHA
Acartia tonsa	48-hr EC_{50}	296.2	1	ECHA
Skeletonema costatum	72-hr EC_{50}	265.7	1	ECHA

Table 3 lists the results of acute aquatic toxicity studies on sodium gluconate (CAS No. 527-07-1).

Table 3: Acute Aquatic Toxicity Studies on Sodium Gluconate (CAS No. 527-07-1)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oryzias latipes	96-hr LC_{50}	>100	2	ECHA
Daphnia magna	48-hr EC_{50}	>1,000	2	ECHA
Desmodesmus subspicatus	72-hr EC_{50}	>1,000	1	ECHA

Chronic Studies
No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for iron gluconate follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels with seawater, but not freshwater species. Acute $E(L)C_{50}$ values are available for fish (>1,000 mg/L), invertebrates (296 mg/L), and algae (266 mg/L). On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported $E(L)C_{50}$ value of 266 mg/L for algae. The $PNEC_{water}$ is 2.7 mg/L.

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.7 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.37/1500) \times 1000 \times 2.7$
$= 0.7$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 18.4 \times 0.02$
$= 0.37$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for benzaldehyde based on the molecular connectivity index (MCI) is 18.4 L/kg (EPA, 2018).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Iron gluconate is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on an estimated BCF of 3.162, iron gluconate does not meet the screening criteria for bioaccumulation.

There are no chronic aquatic toxicity studies on iron gluconate. The acute $E(L)C_{50}$ values are >1 mg/L. Thus, iron gluconate does not meet the screening criteria for toxicity.

The overall conclusion is that iron gluconate is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification
Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008

B. Labeling
Danger

C. Pictogram



(Pubchem 2020)

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air.

Ingestion
Rinse mouth with water and then drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray or fog, carbon dioxide, dry powder.

Specific Exposure Hazards
Burning produces harmful and toxic fumes.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
No special precautions are necessary. Ensure adequate ventilation.

Environmental Precautions
Do not discharge into drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilt
For large amounts: dike spillage and pump off the product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling
Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions

Protect against fire and explosion: prevent electrostatic charge; sources of ignition should be kept well clear, and fire extinguishers should be kept handy.

Storage
Keep container tightly closed and dry. Protect against heat. Store below 25oC.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Occupational exposure standards for the low molecular weight PEGs have not been established.

Engineering Controls
Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment
Respiratory Protection:
Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Body protection must be chosen depending on activity and possible exposure. Safety glasses with side-shields.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information
Not restricted or not applicable

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

NICNAS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

National Institute of Environmental Research (NIER), Korea, Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test in rats. (Study No. B04024), Tested by Biotoxtech, 2004.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Rather, it presents the most critical studies pertinent to the risk assessment of methanol in its use in coal seam gas extraction activities. This dossier on methanol does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on methanol (OECD, 2004a, b), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Methanol

CAS RN: 67-56-1

Molecular formula: CH_4O

Molecular weight: 32.04

Synonyms: Methyl alcohol, carbinol, wood spirits, wood alcohol, methylol, wood, columbian spirits, colonial spirit, columbian spirit, methyl hydroxide, monohydroxymethane, pyroxylic spirit, wood naphtha.

SMILES: CO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-Chemical Properties of Methanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	2	ECHA
Melting Point	-97.8°C	2	ECHA
Boiling Point	64.7°C	2	ECHA
Density	0.79 g/cm^3	2	ECHA
Vapour Pressure	169.27 hPa	2	ECHA
Partition Coefficient (log Pow)	-0.77	2	ECHA
Water Solubility	>1,000 g/L [miscible]	2	ECHA
Flash Point	9.7°C	2	ECHA
Auto flammability	455°C @ 1013 hPa	2	ECHA
Viscosity	0.544 – 0.59 mPa s (dynamic)	2	ECHA
Henry's Law Constant	0.461 Pa m^3/mol	2	ECHA

Methanol is a highly flammable liquid.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Methanol is readily bioavailable. It has a low adsorptive capacity to soils and is unlikely bioaccumulate.

B. Biodegradation

Methanol is readily biodegradable. In a closed bottle test using seawater, there was 84% and 95% degradation after 10 and 20 days, respectively (Price et al., 1974; ECHA). [Kl. score = 2]

In a soil test using [^{14}C]-methanol, there was 53.4% degradation under aerobic conditions after 5 days, as measured by CO_2 evolution; and 46.3% degradation under anaerobic conditions after 5 days, as measured by CO_2 evolution (Scheunert et al., 1987; ECHA). [Kl. score = 2]

C. Environmental Distribution

Adsorption/desorption

The adsorption of methanol was investigated in three different soil types at 6°C (Lokke, 1984; ECHA). There was slight adsorption with the sandy soils tested (percentage organic matter of 0.09% and 0.1% in the samples) and with the clay soil (percentage organic matter was 0.22%). Methanol solutions of concentrations of 0.1, 1.0, 9, and 90 mg/L were used in one-hour exposure adsorption studies; the K_{oc} values were between 0.13 and 0.61 for all soil types and at all concentrations.

D. Bioaccumulation

The BCF of methanol in *Cyprinus carpio* was determined to be 1.0 (Gluth et al. 1985); in *Leuciscus idus*, the BCF was <10 (Hansch and Leo, 1985; Freitag et al. 1985).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Methanol has a low order of acute toxicity (as measured by lethality) by the oral, dermal, and inhalation routes of exposure, as measured by lethality. Sublethal doses, however, have been shown to produce central nervous system (CNS) effects and ocular injury that may result in blindness. This effect has been seen in primates but not in rodents, and is considered to be due to the differences in blood levels of the metabolites. Acute toxicity in humans is characterized in a well-defined pattern, that includes CNS effects, ocular symptoms, and acidosis. Methanol is not irritating to the skin, but it is slightly irritating to the eyes. Repeated exposures by the oral and inhalation routes have not resulted in any systemic toxicity to rodents. Methanol was not carcinogenic to rats or mice in chronic inhalation studies. Increased tumours from methanol in drinking water were reported by Soffritti et al. (2002); however, there are methodological problems with this study and questions have been raised about the validity of the results. Methanol is generally inactive in a variety of *in vitro* and *in vivo* genotoxicity studies. Conflicting results have been obtained concerning the effect of methanol on testicular hormones in rats; nevertheless, methanol does not appear to a male reproductive toxicant. The primate data indicates that methanol is unlikely to be a reproductive hazard in females. Methanol causes developmental effects at very high exposure levels in both rats (≥ 10,000 ppm) and mice (≥ 2000 ppm). There is also some evidence that it is a developmental neurotoxicant in rodents, but not in primates.

B. Toxicokinetics and Metabolism

Several reviews on the metabolism and pharmacokinetics of methanol are available (Kavet and Nauss, 1990; Liesivuori and Savolainen, 1991; Tephly, 1991; IPCS, 1997; OECD, 2004a, b). Methanol is first oxidized to formaldehyde. This initial metabolic step involves different enzymes in rats than in primates and humans, although the rates are similar. A catalase–peroxidase system is primarily responsible for the initial step in rats, whereas alcohol dehydrogenase plays a major role in humans and monkeys. Methanol oxidation can also occur via hepatic microsomal oxidation involving the cytochrome P450 system.

Formaldehyde is converted to formic acid, which is converted to formate and a hydrogen ion. Conversion to formic acid is a two-step process, the second step is irreversible. In the first reaction, formaldehyde combines with reduced glutathione (GSH) to form S-formylglutathione. This is mediated by an NAD-dependent formaldehyde dehydrogenase. In the second reaction, thiolase catalyzes the hydrolysis of S-formylglutathione to form formic acid and GSH. A folate-dependent pathway in the liver is responsible for formate metabolism in both rats and primates. Formate first forms a complex with tetrahydrofolate (THF) that is sequentially converted to 10-formyl-THF (by formyl-THF synthetase) and then to CO2 (by formyl-THF dehydrogenase). THF is derived from folic acid in the diet and is also regenerated in the folate pathway. Although the folate pathway metabolizes formate in both rats and monkeys, rats use the pathway more efficiently.

The dermal uptake rate of liquid methanol applied to the forearm of human volunteers was 11.5 $mg/cm^2/hr$ (Dutkiewicz et al., 1980). The dermal flux for methanol in human skin (epidermis) *in vitro* is 8.29 $mg/cm^2/hr$ (Schueplein and Blank, 1971). When 12 human volunteers immersed one hand into a vessel containing neat methanol for up to 16 min, the maximum methanol concentration in blood was reached 1.9 $\pm$ 1.0 hr after exposure. Delivery rates from the skin into blood lagged exposure by 0.5 hours, and methanol continued to enter the blood for 4 hours following exposure. The average derived dermal absorption rate absorption rate was 8.1 $\pm$ 3.7 $mg/cm^2/hr$. The authors calculated that the maximum concentration of methanol in blood following immersion of one hand in methanol for approximately 20 min is comparable to that reached following inhalation exposures to 200 ppm methanol (Batterman and Franzblau, 1997).

C. Acute Toxicity

The acute oral LD_{50} for rats range from 6,200 to 13,000 mg/kg (Kimura et al., 1971; Welch and Slocum, 1943; Deichman and Mergard, 1948; Smyth et al., 1941). The acute dermal LD_{50} for rabbits was reported to be 20 mL/kg (Rowe and McCollister 1982). The inhalation 4- and 6-hour LC_{50} values in rats are 128.2 and 87.5 mg/L, respectively (BASF, 1980a, b). Sublethal doses, however, produce CNS effects and ocular injury that may result in blindness. This effect has been seen in primates, but not in rodents, and has been attributed to the differences in blood levels of the metabolite, formic acid.

Methanol is metabolized to formate, which is considered to be the ultimate toxicant in acute methanol intoxication in humans. Acute methanol toxicity in humans is characterized by CNS depression, followed by acidosis and ocular injury. Generally, transient CNS effects appear above methanol levels of 200 mg/L and serious ocular symptoms appear above 500 mg/L (OECD, 2004). This blood concentration can transiently be achieved in an adult person (70 kg) by ingestion of 0.4 ml methanol/kg (approximately 0.32 mg/kg). The minimal acute methanol dose to humans that can result in death is considered to be 300 to 1,000 mg/kg by ingestion, and fatalities have occurred in untreated patients with initial methanol blood levels in the range of 1500-2000 mg/L (OECD, 2004).

However, such high blood methanol levels able to cause death are not likely to be achieved through inhalation exposure.

D. Irritation

Methanol is not irritating to the skin of rabbits (BASF, 1975), but it is slightly irritating to the eyes of rabbits (BASF, 1975).

E. Sensitization

Methanol was not considered a skin sensitiser to guinea pigs (BASF, 1979).

F. Repeated Dose Toxicity

Oral

Male and female Sprague–Dawley rats were dosed by oral gavage with 0, 100, 500, or 2,500 mg/kg of methanol for 90 days. There were no differences in body weight gain and food consumption between treated and control animals. Brain weights were decreased in both sexes in the 2,500 mg/kg dose group. Elevated serum glutamic pyruvate transaminase and alkaline phosphatase were noted in the 2,500 mg/kg dose group, but there were no adverse treatment-related effects in the gross pathology and histopathological evaluation. The NOAEL is 500 mg-kg-day (USEPA, 1986).

Sprague-Dawley rats were given in their drinking water 0, 500, 5,000 or 20,000 ppm methanol for 104 weeks, and then the animals were maintained until natural death. The study was conducted by the Ramazzini Foundation which uses their own testing guideline for carcinogenicity studies and not an internationally accepted guideline. Treatment with methanol did not decrease survival. However, there was considerable early mortality; by 18 months, 30% of the male controls had died. In females, there were no differences in survival between controls and treated groups. There was still more early mortality in the females than expected, but it was less pronounced that the males. There was no obvious effect of methanol exposure on water consumption. The 20,000 ppm males and females weighed more than the controls (up to 14% and 7%, respectively) throughout the study. The 5,000 ppm females also weighed more (4%) than the controls at 24 months, but not at earlier time points. There were no body weight differences between the remaining treatment groups and the controls. The calculated methanol doses based on water intake were: 0, 55, 542, and 1,840 mg/kg-day for males; and 0, 67, 630, and 2,250 mg/kg-day for females. Nearly all rats in all dose groups had some pathology in the lung. The finding of lung pathology was consistent regardless of the age at death (not an old age response). The lung pathology included inflammation, dysplasia, or tumours). Lung pathology was present in 70-100% of the first 10% of deaths in each group, including controls (70, 80, 80, 100% in males; and 90, 90, 100, 100% in females at 0, 500, 5,000, and 20,000 ppm). The degree of inflammation in the lungs is difficult to assess because no other lung information was recorded for the rats when a neoplasm in the lung was recorded (Soffritti et al., 2002; Cruzan, 2009; USEPA, 2013a). [Kl. score = 3]

Inhalation

Cynomolgus monkeys or Sprague–Dawley rats were exposed by inhalation to 0, 500, 2,000, or 5,000 ppm (0, 660, 2,620, or 6,552 mg/m3) methanol for 6 h/day, 5 days/ week for 4 weeks. There was no mortality and no clinical signs of toxicity among the monkeys, but there a few signs of eye and nose irritation in the rats. No differences were seen between treated and control groups in body weight gain and organ weights, with the exception being decreased absolute adrenal weight in the 5,000 ppm female monkeys and increased relative spleen weights in the 2,000 ppm female rats. These changes were not considered by the authors to be of biological significance. There were no

treatment-related effects on the ophthalmoscopy, gross pathology or histopathology. The NOAEL for this study is 5,000 ppm (6,552 mg/m^3) (Andrews et al., 1987). [Kl. score = 4]

Groups of four male rats were exposed by inhalation to 0, 200, 2000, or 10,000 ppm (o, 262, 2,621, or 13,104 mg/m3) methanol for 6 hours/day, 5 days/week for 1, 2, 4, or 6 weeks. Additional groups of animals were exposed for 6 weeks followed by a 6-week recovery period. Evaluation of a number of parameters including lung weights, surfactant levels, and enzyme activities did not reveal any adverse effects on the lung. No histopathological examinations were performed (White et al. 1983). [Kl. score = 2]

Male and female F344 rats were exposed by inhalation to 0, 10, 100, or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 104 weeks. The average methanol doses were: 0, 3.7, 37, and 369 mg/kg-day in males; and 0, 5.9, 60, and 599 mg/kg-day for females. There were no treatment-related clinical signs and no effect on survival or food consumption. Lower body weights were seen in the 1,000 ppm females beginning around day 259, but after day 574, there was no difference from controls. Body weights in males were similar across all groups. There were no treatment-related effects on urinalysis, hematology, or clinical biochemistry. Nor was there any treatment-related effects on organ weights or gross lesions. Histopathologic examination showed no statistically significant differences between treated and control animals (NEDO, 1985a). [Kl. score = 2]

Male and female B6C3F1 mice were exposed by inhalation to 0, 10, 100, or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 78 weeks. The average methanol doses were: 0, 9.8, 95, and 947 mg/kg-day in males; and 0, 8.1, 106, and 1,071 mg/kg-day for females. There were no treatment-related clinical signs and no effect on survival or body weight. Food consumption was decreased slightly between months 7 and 12 in the 1,000 ppm females. Urinalysis, hematology, and clinical biochemistry were similar across all groups. No differences were seen in organ weights, gross lesions, or histopathology between treated and control mice. (NEDO, 1985b). [Kl. score = 2]

Dermal

No studies were identified.

G. Genotoxicity

In Vitro Studies

Methanol was not mutagenic to *Salmonella* strains TA97, TA98, TA100, TA1535, TA1537, and TA1538 in *in vitro* bacterial mutation assays with or without metabolic activation (De Flora et al., 1984a, b; Florin et al., 1980; Gocke et al.,1981). Equivocal results were obtained with *Salmonella* strain TA102 in the presence of metabolic activation (De Flora et al. 1984b). Methanol was not mutagenic in a DNA-repair test using various strains of *Escherichia coli* WP2 (De Flora et al. 1984a) and in a forward mutation assay using *Schizosaccharomyces pombe* (Abbondandolo et al. 1980).

Methanol did not induce micronuclei in Chinese hamster lung V79 cells in vitro (Lasne et al., 1984). Methanol was mutagenic in the mouse lymphoma assay in the presence of metabolic activation (McGregor et al., 1985), but it was not mutagenic in a Basc test or in a Drosophila, sex-linked, recessive lethal mutation assay (Gocke et al., 1981). Treatment of primary cultures of Syrian golden hamster embryo cells with methanol did not lead to cell transformation (Heidelberger et al., 1983).

In Vivo Studies

Male C57BL/6J mice were exposed by inhalation 0, 800 or 4,000 ppm methanol, 6 hours/day for five days. There were no increased frequencies of micronuclei in blood cells; sister chromatid exchanges,

chromosomal aberrations, or micronuclei in lung cells; or synaptosomal complex damage in spermatocytes (Campbell et al., 1991).

Normal or folate-deficient mice were given four daily intraperitoneal injections of up to 2,500 mg/kg of methanol. There was no increase in micronucleated erythrocytes in the treated mice compared to the controls (O'Loughlin et al., 1992).

Male and female NMRI mice were given a single intraperitoneal injection of 0, 1,920, 3,200, or 4,480 mg/kg methanol. There was no increase in micronuclei was observed in the bone marrow at any dose level (Gocke et al., 1981).

H. Carcinogenicity

The carcinogenicity studies conducted on methanol were reviewed by Cruzan (2009) and by the USEPA (2013).

Oral

Male and female SD rats were given in their drinking water 0, 500, 5,000, or 20,000 ppm methanol for 104 weeks. This study was conducted by the Ramazzini Foundation, which uses a unique methodology and not the standardized international testing guidelines. There was excessive early mortality, and lung pathology (inflammation, dysplasia, or tumours) was present in 87 to 94% of those dying anytime during the study. An increase in lympho-immunoblastic lymphomas was reported (Soffritti et al., 2002; Cruzan, 2009; USEPA, 2013). [Kl. score = 3]

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 10, 100, or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 104 weeks. The average methanol doses were: 0, 3.7, 37, and 369 mg/kg-day in males; and 0, 5.9, 60, and 599 mg/kg-day for females. There was no increase in tumours in the methanol-exposed rats and mice (NEDO, 1985a). [Kl. score = 2]

Male and female B6C3F1 mice were exposed by inhalation to 0, 10, 100, or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 78 weeks. The average methanol doses were: 0, 9.8, 95, and 947 mg/kg-day in males; and 0, 8.1, 106, and 1,071 mg/kg-day for females. There was no increase in tumours in the methanol-exposed mice (NEDO, 1985b). [Kl. score = 2]

I. Reproductive Toxicity

The reproductive and developmental toxicity studies were reviewed by the NTP Centre for Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003). Conflicting results have been obtained concerning the effect of methanol on testicular hormones in rats; nevertheless, methanol does not appear to a male reproductive toxicant. The primate data indicates that methanol is unlikely to be a reproductive hazard in females. Methanol causes developmental effects at very high exposure levels in both rats (≥ 10,000 ppm) and mice (≥ 2000 ppm); there is also some evidence that it is a developmental neurotoxicant in rodents, but not in primates.

NICNAS concluded in their human health Tier II assessment for methanol: "Based on the data available, [methanol] is not considered to have reproductive or developmental toxicity in humans."

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for methanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A 90-day oral gavage rat study showed elevated serum enzymes and decreased brain weights in the 2,500 mg/kg-day dose group with a NOAEL of 500 mg/kg-day (USEPA, 1986). The NOAEL of 500 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 500/(10 x 10 x 1 x 10 x 1) = 500/1000 = 0.2 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD: Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2 L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

Methanol was not carcinogenic to rats or mice in chronic inhalation studies. Increased tumours from methanol in drinking water were reported by Soffritti et al. (2002); however, there are methodological problems with this study and questions have been raised about the validity of the results. No cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Methanol is a highly flammable liquid.

It does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidising potential.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Methanol exhibits a low toxicity concern for aquatic organisms, terrestrial invertebrates, and plants.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on methanol.

Table 2: Acute Aquatic Toxicity Studies on Methanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill	96-hr LC_{50}	15,400	1	Poirer et al. 1986
Salmo gairdneri	96-hr LC_{50}	20,100	1	Call et al., 1983
Pimphales promelas	96-hr LC_{50}	28,100	1	Call et al., 1983
Daphnia magna	96-hr EC_{50}	18,260	2	Dorn et al., 2012; ECHA
Daphnia magna	48-hr EC_{50}	>10,000	2	Kuehn et al., 1989
Selenastrum capricornutum	96-hr EC_{50}	~22,000	2	Cho et al., 2008; ECHA
Chlorella pyrenoidosa	10-14 d EC_{50}	28,400	2	Stratton and Smith, 1988

Chronic Studies

No adequate chronic studies were identified.

C. Terrestrial Toxicity

The terrestrial toxicity studies on methanol are listed below in Table 3.

Table 3: Terrestrial Toxicity Studies on Methanol

Test Species (Method)	Endpoint	Results (mg/kg soil dw)	Klimisch score	Reference
Earthworm *Eisenia fetida* (OECD 222)	35-d EC_{50} 63-d EC_{50}	17,199 26,646	2	ECHA
Folsomia candida (OECD 232)	28-d EC_{25} 28-d NOEC* (reproduction)	2,842 1,000	1	ECHA
Hordeum vulgare (OECD 208)	14-d EC_{50} 14-d NOEC* (seedling emergence)	15,492 12,000	1	ECHA

Test Species (Method)	Endpoint	Results (mg/kg soil dw)	Klimisch score	Reference
	14-d EC_{25} 14-d NOEC* (shoot dry mass)	2,538 1,555		
	14-d EC_{25} 14-d NOEC* (root dry mass)	2,823 2,592		
	14-d EC_{25} 14-d NOEC* (shoot length)	4,885 2,592		
	14-d EC_{25} 14-d NOEC* (root length)	5,752 4,320		

* Since only EC_{25} values were available from the test results, NOECs were derived graphically from the representing treatment means.

D. Calculation of PNEC

The PNEC calculations for methanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (15,400 mg/L), *Daphnia* (>10,000 mg/L), and algae (22,000 mg/L). There are no well-conducted long-term studies on methanol. Therefore, an assessment of 1,000 has been applied to the lowest reported effect concentration of 10,000 mg/L for *Daphnia*. The $PNEC_{water}$ is 10 mg/L.

PNEC sediment

There are no adequate toxicity studies on sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.3 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.81/1280) \times 1000 \times 10$
$= 6.3$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{soilid}]$
$= 0.8 + [0.2 \times 0.02/1000 \times 2400]$
$= 0.81$

Where:
Kp = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 0.61 x 0.04
= 0.02

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for methanol is 0.61.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil
Experimental results from chronic studies are available for three trophic levels. The lowest NOEC is 1,000 mg/kg soil dry weight for the arthropod *Folsomia candida*. On the basis that the data consists of long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported long-term NOEC of 1,000 mg/kg soil dry weight. The $PNEC_{soil}$ is 100 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009, ECHA, 2008).

Methanol is readily biodegradable and thus it does not meet the screening criteria for persistence.

Based on an experimental BCF of <10 in fish, methanol does not meet the criteria for bioaccumulation.

There are no adequate chronic toxicity studies on methanol. The acute $E(L)C_{50}$ values of methanol in fish, invertebrates and algae is >1 mg/L; thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that methanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 2
Acute Toxicity Category 3 [Oral]
Acute Toxicity Category 3 [dermal]
Acute Toxicity Category 3 [inhalation]
STOT SE Category 1 [optic nerve, central nervous system]

In the EU, there are concentration limits for the STOT SE classification of methanol. This may or may not apply to GHS classifications for Australian SDS.

Concentration range (%):

>10	STOT SE Category 1
>3 and <10	STOT SE Category 2

B. Labelling

Danger

C. Pictograms



The health hazard pictogram is omitted if the STOT SE classification for methanol does not apply. (i.e., concentration of methanol is below the concentration limits).

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

Note: Methanol is used in the drilling mud product ALDACIDE® G ANTIMICROBIAL at a concentration of 0.1% to 1%. The safety and handling of methanol at this concentration in ALDACIDE® G ANTIMICROBIAL will be provided in the dossier on glutaraldehyde, the major constituent of ALDACIDE® G ANTIMICROBIAL.

Occupational Exposure Standards

The workplace exposure standard for methanol in Australia is 200 ppm (262 mg/m^3 as an 8-hr TWA and 250 ppm (328 mg/m^3) as a 15-min STEL. There is also a skin notation indicating that absorption through the skin may be a significant source of exposure.

A. Transport Information

Methanol is used drilling mud product ALDACIDE® G ANTIMICROBIAL at a concentration of 0.1 to 1%. The transportation information for ALDACIDE® G ANTIMICROBIAL will be provided in the dossier on glutaraldehyde, the major constituent of ALDACIDE® G ANTIMICROBIAL.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

Abbondandolo, A. et al. (1980). Mutat. Res. 79: 141 – 150.

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Andrews, L.S., Clary, J.J., Terrill, J.B., and Bolte, H.F. (1987). Subchronic inhalation toxicity of methanol. J. Toxicol. Environ. Health 20: 117-124.

BASF AG (1975). Unpublished data, (XXIV 436), 03 July 1975; cited in OECD-SIDS SIAR on Methanol.

BASF AG (1979). Unpublished data, (78/333), 11 April / 11 July 1979; cited in OECD-S SIDS SIAR on Methanol.

BASF AG (1980a). Unpublished report, (80/158), 07 Aug. 1980; cited in OECD-SIDS SIAR on Methanol.

BASF AG (1980b). Unpublished report, (80/158), 20 Nov. 1980; cited in OECD-SIDS SIAR on Methanol.

Batterman, S.A., and Franzblau, A. (1997). Time-resolved cutaneous absorption and permeation rates of methanol in human volunteers. Int. Arch. Occup. Environ. Health 70: 341-351.

Call, D.J. et al. (1983). Toxicity and metabolism studies with EPA priority pollutants and related chemicals in freshwater organisms, EPA-600/3-83-095, PB83-263665.

Campbell, J.A., Howard, D.R., Backer, L.C., Allen, J.W. (1991). Evidence that methanol does not induce chromosome damage in mice. Mutat. Res. 260 : 257-264.

Cho, C.-W. et al. (2008). The ecotoxicity of ionic liquids and traditional organic solvents on microalga Selenastrum capricornutum. Ecotoxicol. Environ. Saf. 71: 166-171.

Cruzan, G. (2009). Assessment of the cancer potential of methanol. Crit. Rev. Toxicol. 39: 347-363.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Deichman, W.B., and Mergard, E.G. (1948). J. Ind. Hyg. Toxicol. 30: 373 – 378.

Dorn, N. et al. (2012). Discrepancies in the acute versus chronic toxicity of compounds with a designated narcotic mechanism. Chemosphere 87: 742-749.

Dutkiewicz, B., Korczalik, H., and Karwacki, W. (1980). Int. Arch. Occup. Environ. Health 47: 47: 81-88.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health RiskAssessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

De Flora, S. et al. (1984a). Mutat. Res. 133 : 161 – 198.

De Flora, S. et al. (1984b). Mutat. Res. 134 : 159 – 165.

Florin, I. et al. (1980). Toxicol. 18 : 219 – 232.

Freitag, D., Lay, P. and Korte, F. (1985). Environmental Hazard Profile of Organic Chemicals: An experimental method for the assessment of the behaviour of organic chemicals in the ecosphere by means of simple laboratory tests with 14C labelled chemicals. Chemosphere, 14: 1589-1616.

Gluth, G. et al. (1985). Accumulation of pollutants in fish. Comp. Biochem. Physiol., 81C: 273 – 277.

Gocke, E et al. (1981). Mutagenicity of cosmetic ingredients licensed by the European Community. Mutat. Res. 90: 91 – 109.

Hansch, C. and Leo, A.J. (1985). Medchem. Project Issue No.26, Claremont CA, Pomona College.

Heidelberger, C. et al. (1983). Mutat. Res. 114 : 283 – 385.

IPCS (1997). Environmental Health Criteria on Methanol 196, WHO, Geneva.

Kavet , R., and Nauss, K.M. (1990). The toxicity of inhaled methanol vapors. CRC Crit. Rev. Toxicol. 20: 21 – 50.

Kimura, E.T., Ebert, D.M., and Dodge, P.W. (1971). Toxicol. Appl. Pharmacol. 19: 699 – 703.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Kuehn, R. et al. (1989). Water Research, 23: 495-499.

Lasne, C. et al. (1984.) Mutat. Res. 130: 273 – 282.

Liesivuori, J., and Savolainen, H. (1991). Pharmacol. Toxicol. 69: 157 – 163.

Lokke, H. (1984). Leaching of ethylene glycol and ethanol in subsoils. Water, Air, and Soil Pollution 22: 373-387.

McGregor, D.B et al. (1985). Environ. Mutagen. 7(Suppl. 3), A10.

NEDO (1985a). 24-month inhalation carcinogenicity study on methanol in Fischer 344 rats (test no.: 5A-268), Report dated September 30, 1985, 10 volumes. Mitsubishi Kasei Institute for Toxicological and Environmental Sciences, Tokyo.

NED (1985b). 18-month inhalation carcinogenicity study on methanol in B6C3F1 mice (test no.: 4A-223), Report dated March 30, 1985, 9 volumes. Mitsubishi Kasei Institute for Toxicological and Environmental Sciences, Tokyo.

NICNAS. Human Health Tier II Assessment for Methanol; accessed 17 June 2017. Available at: https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=115#cas-A_67-56-1

NTP-CERHR (2003). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Methanol, Center for the Evaluation of Risks to Human Reproduction, National Toxicology Program, U.S. Department of Health and Human Services, NIH Publication, No. 03-4478.

OECD (2004a). IUCLID Data Set for Methanol (CAS No. 67-56-1). Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=39B5D34A-2F5D-4D53-B000-E497B3A3EE89

OECD (2004b). Screening Information Dataset (SIDS) Initial Assessment Report for Methanol (CAS No. 67-56-1). Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=39B5D34A-2F5D-4D53-B000-E497B3A3EE89

O'Loughlin, K. et al. (1992). Environ. Mutagen Soc. 47 (Abstr.).

Poirer S.H., Knuth, L.M., Anderson-Buchou, C.D. et al. (1986). Comparative toxicity of methanol and N,N-dimethylformamide to freshwater fish. Bull. Environ. Contam. Toxicol., 37: 615-621.

Price, K.S. et al. (1974). Brine shrimp bioassay and seawater BOD of petrochemicals. J. Water Pollution Control Fed. 46: 63-77.

Rogers, J.M., Mole, M.L., Chernoff, N., Barbee, B.D., Turner, C.I., Logsdon, T.R., and Kavlock, R.J. (1993). The developmental toxicity of inhaled methanol in the CD-1 mouse, with quantitative dose-response modeling for estimation of benchmark doses. Teratol. 47: 175-188.

Rowe, K., and McCollister, S.B. (1982). In: Patty's Industrial Hygiene and Toxicology, 3rd rev. ed. (G. D. Clayton and F. E. Clayton, eds.), pp. 4527-4708, Wiley, New York.

Scheunert, I. et al. (1987). Biomineralization rates of 14C-labelled organic chemicals in aerobic and anaerobic suspended soil. Chemosphere 16: 1031-1041.

Schuelplein, R.J., and Blank, I.H. (1971). Physiol. Rev. 51: 702-747.

Smyth, H.F., Seaton, J., and Fisher, L. (1941). J. Ind. Hyg. Toxicol. 23: 259 – 268.

Soffritti, M., Belpoggi, F., Cevolani, D., Guarino, M., Padovani, M., and Maltoni, C. (2002). Results of long-term experimental studies on the carcinogenicity of methyl alcohol and ethyl alcohol in rats. In: M.A. Mehlman (Ed.), Carcinogenesis bioassays and protecting public health: commemorating the lifework of Cesare Maltoni and colleagues, pp. 46-69, Bologna, Italy: Ann. N.Y. Acad. Sci.

Stratton, G.W., and Smith, T.M. (1988). Interaction of organic solvents with the green alga Chlorella pyrenoidosa, Bull. Environ. Contam. Toxicol., 40: 736-742.

Tephly, T.R. (1991). The toxicity of methanol. Life Sci. 48: 1031 – 1041.

USEPA. (1986). Rat Oral Subchronic Study on Methanol, U.S. Environmental Protection Agency, Washington, DC. Cited in the U.S. Integrated Risk Information System (IRIS) database for methanol (https://www.epa.gov/iris).

USEPA. (2013a). Toxicological Review of Methanol (Noncancer) (CAS No. 67-56-1) in Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-11/00FA U.S. Environmental Protection Agency, Washington, DC. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0305tr.pdf

USEPA. (2013b). Integrated Risk Information System (IRIS) Chemical Assessment Summary: Methanol (CASRN 67-56-1). Available at:https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0305_summary.pdf

Wagner, R. (1976). Vom Wasser 47, 241-265.

Welch, H., and Slocum, G.G. (1943). J. Lab. Chem. Med. 28: 1440.

White, L.R., Marthinsen, A.B.L., Ricchard, R.J., Eik-Nes, K.B., and Nilsen, O.G. (1983). Biochemical and cytological studies of rat lung after inhalation of methanol vapor. Toxicol. Lett. 17: 1-5.

1,4-DIOXANE-2,5-DIONE, 3,6-DIMETHYL-, (3R-CIS)-, POLYMER WITH (3S-CIS)-3,6-DIMETHYL-1,4-DIOXANE-2,5-DIONE AND TRANS-3,6-DIMETHYL-1,4-DIOXANE-2,5-DIONE
[Polylactide resin]

This dossier on disodium;(9,11-dioxido-5-oxoboranyloxy-2,4,6,8,10,12,13-heptaoxa-1,3,5,7,9,11-hexaborabicyclo[5.5.1]tridecan-3-yl)oxy-oxovorane (designated in this dossier as PLA) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): disodium;(9,11-dioxido-5-oxoboranyloxy-2,4,6,8,10,12,13-heptaoxa-1,3,5,7,9,11-hexaborabicyclo[5.5.1]tridecan-3-yl)oxy-oxovorane

CAS RN: 9051-89-2

Molecular formula: (C6H8O4.C6H8O4.C6H8O4)x

Molecular weight: 128,000–152,000 g/mol

Synonyms: Polylactide resin, polymer of lactic acid, PLA

SMILES: None

II. PHYSICAL AND CHEMICAL PROPERTIES

PLA polymers range from amorphous glassy polymer to semi-crystalline and highly crystalline polymers with a glass transition 60–65 °C and a melting temperature range of 130-180 °C.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

No readily available experimental data are available regarding the environmental fate of the substance. However, given the plasticine nature of the polymer and its high molecular weight, bioconcentration, bioaccumulation, and sorption are not expected to be appreciable.

Data from degradation testing according to standard methods are not available. However, there is evidence that PLA can undergo degradation via isolated and variable bacterial populations (Li et. al. 2008) (Tokiwa and Calabia 2006).

Since there are no available data obtained from standard and there is evidence that bacterial degradation may occur, PLA is not considered a persistent substance for the purposes of this dossier.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

No readily available experimental data are available regarding the human health hazards fate of the substance. In solid form, the substance is essentially non-toxic. Polylactic Acid (PLA) when used in medical implants will degrade within the body over time. It is often used in food handling and it is accepted as GRAS (Generally Recognized as Safe) by the Food and Drug Administration (FDA) and suitable for using in food and beverage packaging Conn et. al. (1995).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Given the noted lack of toxicity information and the GRAS status of the substance, toxicological reference values were not developed according to methodology discussed in enHealth (2012).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

The substance does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

However, it should be noted that flowing product can create electrical charge, resulting sparks may ignite dust or cause an explosion in some concentration ranges.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

No readily available experimental data are available regarding the environmental hazard (aquatic or terrestrial) or fate of the substance.

B. Calculation of PNEC

Given the relative lack available toxicity data and its generally recognized safe status, no PNEC values for water, sediment or soil were derived for the substance.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

Sufficient data are not available to apply the methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008). However, given the biopolymeric nature of the substance, and its expected environmental lability, it is not expected to be ultimately persistent in the environment. As noted above, the substance is not expected to bioconcentrate or bioaccumulate, nor is it believed to be appreciably toxic.

Lastly, it should be noted that, according to the majority of notifications provided by companies to ECHA in CLP notifications, no hazards have been classified (ECHA).

Therefore, PLA is not considered a PBT substance for this dossier.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified

B. Labelling

None

C. Pictogram

None

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention.

Inhalation
Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion
Do not induce vomiting. Get medical attention immediately.

Notes to Physician
All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media
Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards
Dust may form an explosive mixture with air, ignited by sparks or sources of ignition. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide, aldehydes and ketones.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath dust, mist, vapors, or spray Avoid contact with skin, eye, and clothing. Eliminate all sources of ignition.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Eliminate all sources of ignition. Clean up promptly by scoop or vacuum. Sweep up and shovel into suitable containers for disposal. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling
Keep away from heat, sparks, and flame. Avoid contact with eyes, skin, and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage
Keep container tightly closed. Store away from excessive heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for the substance.

Engineering Controls
Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection:
If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection:
Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection:
Use protective clothing chemically resistant to the this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection:
Use chemical goggles.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

The substance is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

EINECS: Substances inventory is not required.
United States TSCA (Toxic Substances Control Act) inventory: Listed
Canadian DSL (Domestic Substances List) inventory: Listed
Japanese ENCS (Existing & New Chemical Substances) inventory: Listed
Korean ECL (Existing Chemical List) inventory: Listed
People's Republic of China register - CRC-SEPA Administration): Listed
New Zealand Inventory of Chemicals (NZIoC): Listed
Australian AICS Inventory: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Conn, R.E, .J.J.Kolstad, J.F.Borzelleca, D.S.Dixler, L.J.Filer Jr, B.N.LaduJr, M.W.Pariza. (1995) Safety assessment of polylactide (PLA) for use as a food-contact polymer. Food and Chemical Toxicology, 33(4): 273-283.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Li F, S. Wang , W. Liu, G. Chen. (2008). Progress on biodegradation of polylactic acid--a review. Acta Microbiologica Sinica. Feb;48(2):262-8.

Yutaka T. and B. P. Calabia 2006. Biodegradability and biodegradation of poly(lactide. Appl Microbiol Biotechnol (2006) 72:244–251.

POLYETHYLENE GLYCOLS (PEG 200 TO PEG 600)

This dossier on the lower molecular weight polyethylene glycols (PEG 200 to PEG 600) presents the most critical studies pertinent to the risk assessment of polyethylene glycols in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on the ethylene glycol category (OECD, 2004). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Poly(oxyethylene) or Poly(ethylene oxide)

CAS RN: 25322-68-3

Molecular formula: $C_{2n}H_{4n+2}O_{n+1}$

Molecular weight: PEG 200 (190 – 210); PEG 300 (285-315); PEG 400 (380-420)

Synonyms: Polyethylene glycol, poly(oxyethylene), poly(oxy-1,2-ethanediyl), α-hydroxy-ω-hydroxy-ethane-1,2-diol

Polyethylene glycols (PEGs) are water-soluble linear polymers formed by the addition reaction of ethylene oxide to an ethylene glycol equivalent. The general formula for polyethylene glycol is: H-$(OCH_2CH_2)_n$-OH where "n" is the average number of repeating oxyethylene groups.

SMILES: O{-}CC(n+} (curly SMILES notation)

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of the Low Molecular Weight PEGs[1]

	PEG 200	PEG 300	PEG 400	PEG 600
Molecular weight range	190-210	285-315	380-420	570-630
Density (g/cm^3)	@ 20°C	1.1249 @ 20°C	1.1255@ 20°C	1.1258 @ 20°C
Melting Point	<65°C	-15 to -8°C	4 to 8°C	15-25°C
Solubility (20°C)	Complete	Complete	Complete	Complete
Viscosity (100°C)	4.3	5.8	7.3	10.8 cSt
Aver. # EO units	4.1	6.4	8.7	13.2
Flash Point (°C)	185/190	218/243	227/263	238/274
Physical Form	Liquid	Liquid	Liquid	Liquid

[1]Technical Data Sheets from The Dow Chemical Company (Dow 2011a,b,c,d).

All of the lower molecular weight PEGs are liquid at room temperature; PEGs with higher molecular weights exist as solids at room temperature.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

No data are available on the low molecular weight PEGs. Data on some of the major constituents indicate that the low molecular weight PEGs are inherently biodegradable, have a low potential for bioaccumulation, and have a high mobility in soil.

B. Biodegradation

No information was located on the low molecular weight PEGs.

Data are available on tetraEG and pentaEG, both being major constituents of PEG 200 (Bailey and Koleste, 1966; OECD, 2004). Both tetraEG and pentaEG are inherently biodegradable. For tetraEG, there was 22% degradation after 20 days in a BOD test and 40% degradation after 28 days in an OECD 301D test (Waggy et al., 1994). For pentaEG, there was 34% degradation after 20 days in a BOD test (OECD, 2004).

C. Bioaccumulation

The experimental value of the log K_{ow} for a low molecular weight PEG was determined to be -0.958 (ECHA). [Kl. score = 1]

Using KOWWIN in EPISUITE™, the estimated log K_{ow} values for tetraEG and pentaEG, the major constituents of PEG 200, are -2.0228 and -2.2972, respectively (EPA 2016). The estimated BCF for both tetraEG and pentaEF using BCFBAF is 3.162.

Thus, the lower molecular weight PEGs are not expected to bioaccumulate.

D. Environmental Distribution

<u>Adsorption/desorption</u>
No experimental data are available for the low molecular weight PEGs. Using KOCWIN in EPISUITE™, the estimated K_{oc} values from log K_{ow} for tetraEG and pentaEG, the major constituents of PEG, are 0.05 and 0.03 L/kg, respectively. The estimated K_{oc} value from the molecular connectivity index (MCI) for tetraEG and pentaEG, the major constituents of PEG, is 10 L/kg (EPA, 2016).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The low molecular weight PEGs are partially absorbed from the small intestine, can undergo metabolism in the body, and both PEG and its metabolites are excreted mainly in the urine. These polymeric compounds are non-toxic by the oral, dermal, and inhalation routes. PEGs are minimally irritating to the skin and eyes, and are not skin sensitizers. Repeated exposures to very high oral doses of PEG 400 produced slight kidney toxicity in rats. The overall evidence is that the low molecular weight PEG polymers are not genotoxic. No developmental toxicity was observed in the animal studies.

B. Toxicokinetics and Metabolism

PEGs of low molecular weight are partially absorbed in the proximal small intestine following oral administration. About 50-65% of PEG 400 was shown to be absorbed in humans (Shaffer et al., 1950).

Metabolism of PEG to acidic metabolites may occur following absorption. PEG and its acidic metabolites appear to be excreted in the urine and bile, with the biliary route playing a major role for the higher molecular weight PEGs (Herold et al., 1982).

C. Acute Toxicity

The oral LD_{50} in rats was reported to range from 25,700 to 32,500 mg/kg (OECD, 2004) and 28,130 mg/kg (OECD, 2004).

The dermal LD_{50} values in rabbits ranges from 14,000 to 20,000 mg/kg (OECD, 2004).

No deaths were reported in rats exposed to an aerosol of 2,516 mg/m^3 PEG 200 for 6 hours (OECD, 2004).

D. Irritation

PEGs (molecular weights not specified) are not irritants (Cavender and Sowinski, 1994).

TetraEG was minimally irritating to human skin (OECD, 2004). PentaEG produced minor transient irritation to rabbit skin (OECD, 2004). Both tetraEG and pentaEG produced minimal transient irritation to the eyes of rabbits (OECD, 2004).

E. Sensitization

PEGs (molecular weights not specified) are not skin sensitizers (Cavender and Sowinski, 1994).

TetraEG was not a skin sensitizer to guinea pigs or to humans (OECD, 2004).

F. Repeated Dose Toxicity

Oral

Male and female F344 rats were dosed by oral gavage with 0, 1,100, 2,800, or 5,600 mg/kg PEG 400 5 days/week for 13 weeks. An additional group of rats (0 and 5,600 mg/kg dose groups) were dosed for 13 weeks followed by a 6-week recovery period. There were no treatment-related deaths or changes in haematology and clinical chemistry parameters. There were loose feces in the mid- and high-dose animals; this was attributed to the bulk cathartic effects of PEG 400. Food consumption and body weights were slightly decreased in the mid- and high-dose animals; although this was attributed to the physical presence of PEG 400 in the gastrointestinal tract, a direct effect of PEG 400 could not be ruled out. Water consumption was increased in all treatment groups possibly due to an increase in serum osmolality due to the absorption of PEG 400. Urine N-acetyl-β-D-glucosaminidase (NAG) activity, osmolality, and specific gravity were increased in a dose-related manner in males of all dose groups. The magnitude of the changes in these parameters in the low-dose group was very slight (only the specific gravity was statistically significant). In females, urinary NAG activity was not significantly altered. Urinary osmolality and specific gravity tended to be increased in females in all dose groups, but only specific gravity of the high-dosed females was statistically significant. Urine pH was decreased in all dosed males and in the mid- and high-dose females. The urinary concentrations

of protein and bilirubin were all increased in males in all dose groups. Following the recovery period, there were no biologically significant changes in hematology, clinical chemistry, or urinalysis in either males or females. Small increases in relative kidney weights were seen in the treated animals and was attributed to the osmotic effect of PEG 400 and/or metabolites in the urine. There were no histopathologic effects noted in the kidneys or urinary bladder. The results suggest a slight, reversible kidney toxicity in the 2,800 mg/kg males and in the 5,600 mg/kg males and females, based on increased concentration of protein and bilirubin, urinary vascular cell findings, and NAG activity. The NOAEL for this study is 2,800 mg/kg-day (Hermansky et al., 1995; ECHA). [Kl. score = 2]

Male and female rats were fed in their diet 0, 2, 4, 8, 16, or 24% PEG 400 (0, 1,000, 2,000, 4,000, 8,000, or 12,000 mg/kg-day) for 90 days. No effects were seen in the rats at doses up to 8% in the diet. At 16% in the diet, liver and kidney weights were increased compared to the controls, and a decrease in body weight gain was observed. The NOAEL for this study is 8% in the diet or 4,000 mg/kg-day (Smyth et al., 1995; ECHA) [Kl. score = 4]

Male and female rats were fed in their diet 0, 1, 2, 4, or 8% PEG 400 (0, 500, 1,000, 2,000, or 4,000 mg/kg-day) for two years. The male rats in the 4% dose group grew slightly less than the control males. No other effects were reported. The NOAEL is 2% in the diet or 2,000 mg/kg-day (Smyth et al. 1995; ECHA) [Kl. score = 4]

Inhalation
No studies were located on the lower molecular weight PEGs.

Dermal
No studies were located on the lower molecular weight PEGs.

G. Genotoxicity

No studies on PEG 400 or PEG 600 were located.

PEG 200 (containing ~29% tetraEG) was tested *in vitro* for genotoxicity in a Chinese hamster epithelial liver cell chromosomal aberration assay. A dose-related increase in chromosomal aberrations was observed (Biondi et al., 2002; OECD, 2004). PEG 200 (26% tetraEG) was also tested in an *in vivo* rat bone marrow chromosomal aberration test. A significant marginal increase was observed in the male rats at the 12-hour harvest time point at doses of 2,500 and 5,000 mg/kg; the increase was dose-related indicating a clear positive response.

PEG 200 contains diethylene glycol DEG), triethylene glycol (TEG), tetraEG and pentaEG; all have been tested for genotoxicity. PEG 200 also contains several glycols of higher molecular weights, which have not been assessed for mutagenicity.

Mutagenicity studies in bacteria and *in vitro* mutagenicity studies in mammalian cells have been conducted for DEG and TEG, and the results have been uniformly negative (OECD, 2004). The results of *in vitro assays* of EG and DEG for chromosomal aberrations (CHO chromosomal aberration and sister chromatid exchange assays) have also been uniformly negative (OECD, 2004). DEG and TEG have not been tested *in vivo* for genotoxicity.

TetraEG has been found to cause chromosome aberrations *in vitro* (OECD, 2004); however, three assays for chromosomal effects *in vivo* have been either negative or equivocal. These *in vivo* studies include a negative rat dominant lethal test; a negative rat bone marrow chromosome aberration test; and an equivocal mouse peripheral blood micronucleus assay (OECD, 2004). A more recent

statistical reanalysis of the rat chromosome aberration study (White and Douglas, 2003; OECD, 2004) judged the overall result to be equivocal because of a marginal association and dose-related trends for either sex but at different harvest times, and a significant effect of treatment limited to the lowest doses in females at the 24 hour harvest and males at the 12 hour harvest. However, inspection of the overall data from this assay show these two values to be isolated to the lowest exposure animals and the dose effect trends to be inverse, i.e. decreasing with increasing doses without evidence of cytotoxicity from treatments. The reason for the equivocal designation for the tetraEG mouse micronucleus test was a weak statistically significant increase in micronuclei in males only at a single time point and without a dose-response.

PentaEG was not mutagenic in the Ames test or in mammalian cells *in vitro* in the CHO/HGPRT assay (OECD, 2004). A mouse bone marrow micronucleus test of crude pentaEG (70% pentaEG, 19% tetraEG) was assessed as negative by the original investigators but deemed to be equivocal after statistical reanalysis (White and Douglas, 2003; OECD, 2004) using non-parametric contingency table analyses and trend tests. However, inspection of the primary data reveals that this reanalysis was influenced by a single uncharacteristically low micronuclei control value in one sex (females) at a single time point, indicating that the test result is biologically negative.

H. Carcinogenicity

No studies were located.

I. Reproductive Toxicity

No studies have been conducted on PEGs.

Repeat dosing with tetraEG at doses up to 6,386 mg/kg-day for 14 days or 2,000 mg/kg-day for 4 weeks produced no notable changes in the histopathology of the testes and epididymides of rats (OECD, 2004).

J. Developmental Toxicity

No developmental effects were seen in rats dosed orally up to 10,000 mg/kg-day PEG 200 (OECD, 2004).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for the lower molecular PEGs follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>
No toxicity was seen in rats given 2,000 mg/kg-day PEG 400 in their feed for two years. The NOAEL of 2,000 mg/kg-day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

<u>Oral Reference Dose (oral RfD)</u>
Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 2,000/(10 x 10 x 1 x 1 x 1) = 2,000/100 = 20 mg/kg-day

Drinking water guidance value
Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (20 x 70 x 0.1)/2 = 70 mg/L

B. Cancer

There are no carcinogenicity studies on the low molecular weight PEGs. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

The low molecular weight PEGs do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The low molecular weight PEG polymers are not toxic to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies conducted on the low molecular weight PEGs and their major constituents.

Table 2: Acute Aquatic Toxicity Studies on the Low Molecular Weight PEGs and Their Major Constituents

Test Substance (CAS No.)	Test Species	Endpoint	Results (mg/L)	Reference
PEG (molecular weight unknown)	*Poecilia reticulata*	96-hr LC_{50}	>100	ECHA
TetraEG (112-60-7)	*Pimephales promelas*	96-hr LC_{50}	>10,000	OECD, 2004; ECHA
PentaEG (4792-15-8)	*Pimephales promelas*	96-hr LC_{50}	>50,000	OECD, 2004
TetraEG (112-60-7)	*Daphnia magna*	48-hr EC_{50}	7,746	OECD, 2004; ECHA
PentaEG (4792-15-8)	*Daphnia magna*	48-hr EC_{50}	>20,000	OECD, 2004
PentaEG (4792-15-8)	*Pseudokirchnerialla subcapitata*	72-hr EC_{50} NOEC	>100 100	OECD, 2004

Chronic Studies

No chronic aquatic toxicity studies were located on the low molecular weight PEGs. Table 3 lists the results of chronic aquatic toxicity studies on triethylene glycol, a constituent of PEG 200.

Table 3: Chronic Aquatic Toxicity Studies on Triethylene Glycol

Test Substance (CAS No.)	Test Species	Endpoint	Results (mg/L)	Reference
TEG (112-60-7)	*Pimephales promelas*	7-d NOEC	15,380 (weight)	Pillard, 1995; ECHA
TEG (112-60-7)	*Daphnia magna*	7-d NOEC	8,590 (reproduction)	Pillard,1995; ECHA

C. Terrestrial Toxicity

No studies were located.

D. Calculation of PNEC

The PNEC calculations for the low molecular weight PEGs follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels for the low molecular weight PEGs and their major constituents. Acute E(L)C_{50} values are available for fish (>100 mg/L), *Daphnia* (7,746 mg/L), and algae (>100 mg/L). Chronic toxicity data are available on triethylene glycol (fish and invertebrates) and pentaEG (algae), with the lowest NOEC being 100 mg/L for algae. On the basis that the data consists of short-term results from three trophic levels and long-term results of three trophic levels, an assessment factor of 10 has been applied to chronic NOEC of 100 mg/L for algae. The $PNEC_{water}$ is 10 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 7.7 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.99/1280) \times 1000 \times 10$
$= 7.7$

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.4/1000 \times 2400]$
$= 0.99$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 10 \times 0.04$
$= 0.4$

Where:

K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for tetraEG and pentaEG, major constituents of PEG 200, is 10 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 1.3 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.2/1500) \times 1000 \times 10$
$= 1.3$

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 10 \times 0.02$
$= 0.2$

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for tetraEG and pentaEG, major constituents of PEG, is 10 L/kg.

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

No information is available on the low molecular weight PEGs; however, constituents tetraEG and pentaEG are inherently, but not readily, biodegradable. Thus, the low molecular weight PEGs are expected to meet the screening criteria for persistence.

No information is available on the low molecular weight PEGs; however, constituents tetraEG and pentaEG have log K_{ow} values of -2.0 and -2.3, respectively. Thus, the low molecular weight PEGs are not expected to meet the screening criteria for bioaccumulation.

There are no chronic aquatic toxicity studies on the low molecular weight PEG; however, the NOECs from chronic aquatic toxicity studies conducted on constituents TEG and pentaEG are >0.1 mg/L. Thus, the low molecular weight PEGs are not expected to meet the screening criteria for toxicity.

The overall conclusion is that the low molecular weight PEGs are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air.

Ingestion
Rinse mouth with water and then drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray or fog, carbon dioxide, dry powder.

Specific Exposure Hazards
Burning produces harmful and toxic fumes.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
No special precautions are necessary. Ensure adequate ventilation.

Environmental Precautions
Do not discharge into drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilt
For large amounts: dike spillage and pump off the product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions
Protect against fire and explosion: prevent electrostatic charge; sources of ignition should be kept well clear, and fire extinguishers should be kept handy.

Storage
Keep container tightly closed and dry. Protect against heat. Store below 25°C.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Occupational exposure standards for the low molecular weight PEGs have not been established.

Engineering Controls
Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment
Respiratory Protection: Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Body protection must be chosen depending on activity and possible exposure.

Other Precautions: Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

The low molecular weight PEGs are not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Bailey, F.E., Jr., and Koleske, J.V. (1966). Chapter 23. Configuration and hydrodynamic properties of the polyoxyethylene chain in solution. In: Nonionic Surfactants. Edited by M.J. Schick, Marcel Dekker, Inc., New York; cited in OECD 2004.

Biondi, O., Motta, S., and Mosesso, P. (2002). Low molecular weight polyethylene glycol induced chromosome aberrations in Chinese hamster cells cultured *in vitro*. Mutagenesis 17: 261-264.

Cavender, F.L., smf Sowinski, E.J. (1994). Glycols. In: Patty's Industrial Hygiene and Toxicology, Fourth Edition, Volume 2, Part F, Ed. By G.D. Clayton and F.E. Clayton, pp. 4645-4719, John Wiley & Sons, Inc.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Dow (2011a). Technical Data Sheet: CARBOWAX™ Polyethylene Glycol (PEG) 200. The Dow Chemical Company. Available at: http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0889/0901b80380889477.pdf?filepath=polyglycols/pdfs/noreg/118-01796.pdf&fromPage=GetDoc

Dow (2011b). Technical Data Sheet: CARBOWAX™ Polyethylene Glycol (PEG) 300. The Dow Chemical Company. Available at: http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0889/0901b80380889737.pdf?filepath=polyglycols/pdfs/noreg/118-01797.pdf&fromPage=GetDoc

Dow (2011c). Technical Data Sheet: CARBOWAX™ Polyethylene Glycol (PEG) 400. The Dow Chemical Company. Available at: http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0887/0901b80380887901.pdf?filepath=polyglycols/pdfs/noreg/118-01798.pdf&fromPage=GetDoc

Dow (2011d). Technical Data Sheet: CARBOWAX™ Polyethylene Glycol (PEG) 600. The Dow Chemical Company. Available at: http://msdssearch.dow.com/PublishedLiteratureDOWCOM/dh_0887/0901b80380887904.pdf?filepath=polyglycols/pdfs/noreg/118-01800.pdf&fromPage=GetDoc

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Hermansky, S.J., Neptun, D.A., Loughran, K.A., and Leung, H.W. (1995). Effects of polyethylene glycol (PEG 400) following 13 weeks of gavage treatment in Fischer-344 rats. Fd. Chem. Toxicol. 33: 139-149

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Pillard, D. (1995). Comparative toxicity of forumulated glycol deicers and pure ethylene and propylene glycol to Ceriodaphnia dubia and Pimephales promelas. Environ. Toxicol. Chem. 14: 311-315.

Shaffer, C.B., Crichfield, F.H., and Nair, J.H. III (1950). The absorption and excretion of a liquid polyethylene glycol. J. Amer. Pharmaceut. Assoc. 39: 340-343.

Smyth, Jr., H.F., Carpenter, C.P., and Weil, C.S. (1955). The chronic oral toxicology of the polyethylene glycols. J. Amer. Pharm. Assoc. 44: 27-30.

OECD (2004). SIDS Initial Assessment Report on the Ethylene Glycol Category: Ethylene Glycol (CAS No. 107-21-1), Diethylene Glycol (CAS No. 111-46-6), Triethylene Glycol (CAS No. 112-27-6), Tetraethylene Glycol (CAS No. 112-60-7), Pentaethylene glycol (CAS No. 4792-15-8).

Herold, D.A., Rodeheaver, G.T., Bellamy, W.T., Fitton, L.A., Bruns, D.E., and Edlich, R.F. (1982). Toxicity of topical polyethylene glycol. Toxicol. Appl. Pharmacol. 65: 329-335.

U.S. Environmental Protection Agency [EPA] (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

POLYPROPYLENE GLYCOL

This dossier on polypropylene glycol presents the most critical studies pertinent to the risk assessment of polypropylene glycol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA) and on a Cosmetics Ingredient Review (CIR) on polypropylene glycol (Andersen, 1994). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Propane-1,2-diol, propoxylated

CAS RN: 25322-69-4

Molecular formula: $(C_3H_6O)_n$-H_2O

Molecular weight: Variable

Synonyms: Propane-1,2-diol propoxylated; polyoxypropylene; oxirane, methyl-, homopolymer; propylene oxide homopolymer; propylene oxide, propylene glycol polymer; poly[oxy(methyl-1,2-ethanediyl)], alpha.-hydro-.omega.-hydroxy-; alpha-hydro-omega-hydroxypoly(oxy(methyl-1,2-ethanediyl)); alpha-hydro-omega-hydroxypoly(oxypropylene)

Polypropylene glycol is a polymer of propylene oxide, with a minimal of three propylene oxide units.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of Selected Polypropylene Glycols

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, colorless, viscous liquid	4	ECHA
Melting Point*	< -150°C	1	ECHA
Boiling Point*	287°C	1	ECHA
Density*	1.012 @ 20°C	1	ECHA
Vapour Pressure**	8.39×10^{-4} @ 20°C 1.35×10^{-3} @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})***	<0.3 to 0.9 (measured)	1	ECHA
Water Solubility*	miscible	1	ECHA
Flash Point*	151°C	1	ECHA
Auto flammability*	305°C	1	ECHA
Viscosity**	78.34 mPa s @ 20°C 27.37 mPa s @ 20°C	1	ECHA
Henry's Law Constant	-	-	-

*Polypropylene glycol (MW 260)

**Polypropylene glycol (MW 250)

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Polypropylene glycols are readily biodegradable. They are not expected to bioaccumulate. Polypropylene glycols have low potential to adsorb to sediment and soil.

B. Biodegradation

In an OECD 301F test, polypropylene glycol (identified as Polyol PD 230, MW 260) was degraded 2.1% after 7 days; 60.6% after 14 days; and 86.6% after 28 days. It is considered readily biodegradable (ECHA). [Kl. score = 1]

C. Environmental Distribution

Adsorption/desorption

In an OECD TG 121 test, the K_{oc} of polypropylene glycol (identified as Polyol PD 230, MW 260) was determined to be <17.8. The test material showed weak surface-active properties; it is also a UVCB mixture of homologous components. So, the analytical method may have produced results that are confounded by these properties (ECHA). [Kl. score = 2]

D. Bioaccumulation

No experimental studies are available. Based on the log K_{ow} of <0.3 to 0.9, polypropylene glycols are not expected to be bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute oral toxicity of polypropylene glycols varies from moderately to non-toxic, depending on the molecular (toxicity decreases with increasing molecular weight). These substances are non-toxic by the dermal route. Polypropylene glycols are not skin and eye irritants; nor are they skin sensitizers. Repeated dose toxicity studies showed minimal systemic toxicity in rats given oral doses or rabbits given dermal applications of polypropylene glycols. These substances are not genotoxic. In a screening study, no reproductive or developmental effects were seen in rats dosed orally with a substance that is structurally related to polypropylene glycols.

B. Acute Toxicity

Acute oral toxicity studies on polypropylene glycols of various molecular weights (300 to 3,900) have indicated LD_{50} values in rats ranging from 500 to >40,000 mg/kg (Andersen, 1994).

In acute dermal toxicity studies, doses of PPG 1025 (20 mL/kg) and PPG 2025 (20 mL/kg) did not cause death to rabbits. Two of five rabbits dosed with 20 mL/kg PPG 425 and one of five dosed with 10 mL/kg PPG 425 died (Andersen, 1994).

No acute inhalation studies on polypropylene glycol were identified.

C. Irritation

Skin irritation was not noted after PPG 425, PPG 1025, or PPG 2025 was applied once to the skin of rabbits or when applied a total of eight times to the same area within 4 hours (Andersen, 1994).

PPGs 425, 1025, and 2025 were classified as harmless agents in rabbits in another ocular irritation study; PPG 1200 induced slight, transient ocular irritation in an albino rabbit (Andersen, 1994).

D. Sensitisation

Polypropylene glycol (MW 260) was considered a non-sensitiser in a mouse local lymph node assay (LLNA) (ECHA) [Kl. score = 1]. Neither skin irritation nor sensitisation reactions were observed in 300 human subjects who received continuous and repeated dermal applications of undiluted PPG 2000 (Andersen, 1994).

E. Repeated Dose Toxicity

Oral

PPG 2000 was administered to rats over a period of 100 days. Concentrations of 0.1, 0.3, 1.0, and 3.0% were administered in oral doses of 50 to 1,500 mg/kg-day. There were no adverse effects noted at concentrations of 0.1 to 1.0%. Slight decreases in growth were observed after the administration of 3% PPG 2000. The NOAEL is 1% (500 mg/kg-day) in the diet (Andersen, 1994).

In a 90-day study, PPG 2000 was administered orally to rats in doses ranging from 275 to 501 mg/kg-day. There was no evidence of adverse histopathologic, hematologic, or clinical chemistry effects in any of the animals tested. Body weight effects (not specified) were noted at the highest dose tested. The NOAEL is ~500 mg/kg-day (Andersen, 1994).

PPG 750 was administered to rats over a period of 100 days. Concentrations of 0.1 and 1% were administered at doses of 50 and 500 mg/kg-day. PPG 750 (0.1%) did not induce any adverse effects. However, in the group dosed with 1% PPG 750, there was a slight increase in liver and kidney weights; there were no histological changes. Neither of the doses resulted in a central nervous system stimulatory effect. The NOAEL is 500 mg/kg-day (Andersen, 1994).

A rat 28-day oral gavage study was conducted on triethanolamine, propoxylated (CAS No. 37208-53-0), a structurally related substance to polypropylene glycol. Male and female Wistar rats were dosed with 0, 100, 300, or 1,000 mg/kg-day. There were no treatment-related deaths and no clinical signs of toxicity. Haematological and clinical chemistry parameters measured in the study were similar across all groups. There were no gross necropsy or histopathological changes that were considered to be treatment-related. The NOAEL for this study is 1,000 mg/kg-day (ECHA). [Kl. score = 1]

Inhalation

No studies are available.

Dermal

PPG-2000, at doses of 1, 5, or 10 ml/kg, was applied to the skin of rabbits 24 hours/day, 5 days/week for three months. It was reported that there was a slight reduction in growth in the 5 and 10 ml/kg groups; no effects were seen at 1 mL/kg (Andersen, 1994).

F. Genotoxicity

In Vitro Studies

Polypropylene glycol (MW 260) was not mutagenic to *S. typhimurium* strains TA1535, TA1537, TA102, TA98, and TA100 in the absence or presence of metabolic activation (ECHA).

In Vivo Studies

No studies are available.

G. Reproductive/Developmental Toxicity

No studies are available on polypropylene glycol.

A reproductive and developmental screening toxicity study (OECD 421) was conducted on triethanolamine, propoxylated (CAS No. 37208-53-0), a structurally related substance to polypropylene glycol. Male and female Wistar rats were dosed by oral gavage with doses of 0, 100, 300, or 1,000 mg/kg-day. Transient salivation was noted in the high-dose parental animals. There were marginal body weight gains in females in all dose groups during the pre-mating period, and a slight body weight loss in the high-dose females during lactation. There were no reproductive or developmental effects that were considered treatment-related. The NOAEL for reproductive and developmental toxicity is 1,000 mg/kg-day (ECHA). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for polypropylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

Several rat subchronic toxicity studies conducted on polypropylene glycol showed an NOAEL of 1% polypropylene glycol in diet (500 mg/kg-day). In one study, it was reported that there was a slight increase in liver and kidney weights, but no data was provided to determine if the change in organ weights were statistically significant. Nevertheless, these organ weight changes may not be considered adverse since there were no accompanying histopathologic changes. No adverse effects were seen in rats given oral doses of up to 1,000 mg/kg-day for four weeks of a substance that is structurally similar to polypropylene glycol.

The NOAEL of 500 mg/kg-day from the polypropylene glycol studies will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 500/(10 x 10 x 1 x 10 x 1) = 500/1,000 = 0.5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG 2011)
Proportion of water consumed = 10% (ADWG 2011)
Volume of water consumed = 2L (ADWG 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 2 mg/L

B. Cancer

No carcinogenicity studies are available on the propylene glycols. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Polypropylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Polypropylene glycol is low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Table 2 lists the results of acute aquatic toxicity studies on polypropylene glycol.

Table 2: Acute Aquatic Toxicity Studies on Polypropylene Glycol

Test Species	Endpoint	Results (mg/L)	Kl. score	Reference
Danio rerio	96-h LC_{50}	>100	1	ECHA
Daphnia magna	48-h EC_{50}	105.8	1	ECHA
Desmodesmus subspicatus	72-h EC_{50}	>100	1	ECHA

Chronic Studies
No studies on polypropylene glycol are available.

There is a chronic *Daphnia* reproduction study on D-glucitol, propoxylated (CAS No. 52625-13-5), with an MW of 600. The 21-day NOEC from this study is >10 mg/L (ECHA).

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for polypropylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (>100 mg/L), *Daphnia* (105.8 mg/L), and algae (>100 mg/L). The only chronic toxicity study on polypropylene glycol is an algal study. However, a chronic *Daphnia* study has been conducted on D-glucitol, propoxylated (CAS No. 52625-13-5), a structurally similar substance to polypropylene, with a NOEC of >10 mg/L On the basis of the short-term results from three trophic levels and long-term results from two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC value of 10 mg/L for invertebrates. The $PNEC_{water}$ is 0.2 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.18 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (1.14/1280) \times 1000 \times 0.2$
$= 0.18$

Where:
$K_{sex\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + (0.2 \times Kp_{sed}/1000 \times BD_{solid}$
$= 0.8 + (0.2 \times 0.71/1000 \times 2400)$
$= 1.14$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid}= bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 17.8 \times 0.04$
$= 0.71$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for polypropylene glycol is 17.8.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.05 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.36/1500) \times 1000 \times 0.2$
$= 0.05$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 17.8 \times 0.02$
$= 0.36$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for polypropylene glycol is 17.8.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Polypropylene glycol is readily biodegradable; thus it does not meet the screening criteria for persistence.

Based on the log K_{ow} of <0.3 to 0.9, polypropylene glycol does not meet the screening criteria for bioaccumulation.

There are no chronic toxicity studies on polypropylene glycol. The acute $E(L)C_{50}$ values of polypropylene glycol is >1 mg/L in fish, invertebrates, and algae. Also, an NOEC from structurally similar substance (D-glucitol, propoxylated) is >0.1 mg/L. Thus it does not meet the screening criteria for toxicity.

The overall conclusion is that polypropylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. Remove contacts, if possible. If symptoms persist, seek medical attention.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
If swallowed, seek medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Burning produces harmful and toxic fumes. Combustion products may include: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus and protective clothing.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Spilled material may cause a slipping hazard.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

D. Storage and Handling

General Handling
Do not swallow. Wash thoroughly after handling.

Storage
Keep container closed when not in use. Store in a dry place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure limit for propylene glycol.

Engineering Controls
Use in a well-ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal Protection Equipment
Respiratory Protection: Not normally needed. But if significant exposures are possible then the following respirator is recommended: organic vapour respirator with a dust/mist filter.

Hand Protection: Chemical protective gloves.

Skin Protection: Normal work coveralls.

Eye protection: Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Polypropylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Andersen F.A. (1994) Final report on the safety assessment of propylene glycol and polypropylene glycols. Int. J. Toxicol. 13: 437- 491.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol, Pharmacol. 25:1-5.

POTASSIUM CHLORIDE

This dossier on potassium chloride presents the most critical studies pertinent to the risk assessment of potassium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on potassium chloride (OECD, 2001a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Potassium chloride

CAS RN: 7747-40-7

Molecular formula: KCl

Molecular weight: 74.55 g/mol

Synonyms: Potassium chloride

SMILES: [Cl-] [K+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Potassium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid; white crystals	2	ECHA
Melting Point	770°C @ 101.3 kPa	1	ECHA
Boiling Point	1,407°C (pressure not provided)	2	OECD, 2001a,b
Density	1984 kg/m^3	2	ECHA
Vapour Pressure	5.73 hPa @ 906°C	2	OECD, 2001a,b
Partition Coefficient (log Kow)	-	-	-
Water Solubility	255 g/L @ 25°C	2	Lide, 2009; ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Potassium chloride (KCl) dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of potassium (K^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH and organic matter. Potassium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (OECD, 2001b).

Potassium (K^+) and chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001b; Ganong, 1995). Neither potassium chloride nor its dissociated ions are expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Potassium chloride has low acute toxicity by the oral route. It is not a skin or eye irritant. Long-term studies in rats fed potassium chloride showed no systemic toxicity or carcinogenic effects. Potassium chloride has shown some genotoxic effects in *in vitro* assays; these occurred at high concentrations of potassium chloride and is thought to be due to a disruption of the osmotic balance of the cells. No *in vivo* genotoxicity studies have been conducted on potassium chloride. There were no developmental effects in pregnant female rats and mice given potassium chloride in their diet.

B. Toxicokinetics and Metabolism

Potassium chloride dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium is an essential nutrient: it has a number of critical roles, one of which is that it is the principal cation involved in maintaining the osmotic balance of bodily fluids (Ganong, 1995). Both potassium and chloride ions are involved in regulating the acid-base balance of the body (Ganong, 1995).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 3,020 mg/kg (Boyd and Shanas, 1961) [Kl score = 2].

No acute toxicity studies by the dermal or inhalation route were identified.

D. Irritation

Potassium chloride did not produce an irritant response in an *in vitro* skin irritation (OECD TG 439) test (ECHA) [Kl score = 1].

Potassium chloride did not produce an irritant response in an *in vitro* eye irritation test (ECHA) [Kl score = 2].

E. Sensitisation

No studies were identified.

F. Repeated Dose Toxicity

<u>Oral</u>

Male F344/Slc rats were given 0, 0.25, 1, 5 or 5% potassium chloride in their feed for two years. The mean daily intake was calculated to be 0, 110, 450 or 1,820 mg/kg/day, respectively. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the respective dose groups. Nephritis was predominant in all groups, including the controls. The only treatment-related effect was gastritis (inflammation of the stomach lining). The incidence of gastritis and ulcers were 6%, 18%, 18% and 30% in the 0, 110, 450 and 1,820 mg/kg/day groups, respectively. The gastritis was thought to be indicative of a localised effect due to the irritating nature of the test material. The NOAEL for

systemic effects is 1,820 mg/kg/day, the highest dose tested (Imai et al., 1968; OECD 2001a,b) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. Due to the reduction of feed intake, the mean test substance intake and mean body weight decreased in time. The mean daily intake of potassium chloride was not calculated. There was hypertrophy of the zona glomerulosa in the adrenals (24/50 treated rats versus 4/50 in controls); and cystitis in the urinary bladder (males: 3/59; females 3/50) and single epithelial hyperplasia of the bladder (males 3/50; females 2/50) (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

G. Genotoxicity

In Vitro Studies

Potassium chloride was not mutagenic to *Salmonella typhimurium* strains TA100, TA 1535, TA 1537 and TA 98 strains in an *in vitro* bacterial mutation assay in the absence or presence of metabolic activation (Mortelmans et al., 1986).

Potassium chloride was weakly mutagenic in two separate L5178Y mouse lymphoma assays (Myhr and Caspary,1988; Mitchell et al., 1988). It was mutagenic at 4,000 and 5,000 μg/mL in the presence of metabolic activation in one study, and mutagenic at 7,000 μg/mL in the absence of metabolic activation. The authors stated that these responses are due to high salt concentrations which affect the ionic balance and osmotic pressure of the medium, inducing mutations in cells surviving the treatment.

Potassium chloride induced a significant increase in chromosomal aberrations in Chinese Hamster lung fibroblasts (V79) cells only at the highest test dose (12,000 μg/mL) in the absence of a metabolic activation system. Measurements of the osmotic pressure of the medium showed a two-fold increase at this test compound concentration when compared to the normal medium (530 mOsmol/kg versus 253 mOsmol/kg) (OECD, 2001b).

There are two other reports on the effect of potassium chloride on the formation of chromosome aberrations in Chinese hamster ovary cells (CHO). In these studies potassium chloride concentrations of 75 and 80 mM (approximately 5,500 and 6,000 μg/mL) resulted in 19% and 28% aberrant cells, respectively. An increased number of chromosome aberrations was observed with potassium chloride concentrations that reduced cell survival of 40% or more. The increases in mutagenicity and chromosome aberrations observed in these studies have been considered to be related to cytotoxicity resulting from the high potassium chloride concentrations used (Brusick, 1988).

The reported mutagenic effect of potassium chloride most probably results from a disruption of the osmotic balance of cells with a subsequent interference with chromosomal stability. This may result in the clastogenic effects (DNA breakage and chromosome structural instability) due to K^+ effects on sequestering of Mg^{++} ions required for normal maintenance of chromatin integrity (OECD, 2001b).

In Vivo Studies

No studies have been identified.

H. Carcinogenicity

Oral

F344/Slc male rats were given 0, 110, 450 or 1,820 mg/kg/day potassium chloride in feed for two years. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the 0, 110, 45 and 1,820 mg/kg/day groups. There was no increased incidence of tumours that were considered to be treatment-related (Imai et al., 1968) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. There were no treatment-related differences in tumour response among the groups (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

I. Reproductive Toxicity

No studies were identified.

J. Developmental Toxicity

Pregnant Wistar rats were given doses of 3.1 to 310 mg/kg potassium chloride by oral gavage during gestation days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 310 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

Pregnant CD-1 mice were given doses of 2.35 to 235 mg/kg potassium chloride by oral gavage during gestation Days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 235 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for potassium chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Two chronic rat feeding studies have been conducted on potassium chloride: only the study by Imai et al. (19686 was conducted with multiple doses and provided mean daily intake values. In this study, the only treatment-related effects were associated with chronic irritation in the gastrointestinal tract (gastritis and ulcers), a localised effect due to the irritating properties of the test material. No systemic toxicity was observed at any of the doses tested. The NOAEL for systemic toxicity in this study is 1,820 mg/kg/day, the highest dose tested. The NOAEL of 1,820 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subacute to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4(10 x 10 x 1 x 1 x 1) = 1,820/100 = 18 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD:

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (18 x 70 x 0.1)/2 = 63 mg/L

Australian Drinking Water Guidelines

The Australian drinking water guideline value for chloride is 250 mg/L based on aesthetics (ADWG, 2011).

B. Cancer

Potassium chloride was not carcinogenic to rats in two chronic feeding studies. Therefore, no cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Potassium chloride does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Potassium chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

The results of the acute toxicity studies conducted on potassium chloride are presented in Table 2.

Table 2: Acute Aquatic Toxicity Studies on Potassium Chloride

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	880	2	Mount et al., 1997; ECHA
Daphnia magna	48-hour EC_{50}	660	2	Mount et al., 1997; ECHA
Ceriodaphnia dubia	48-hour EC_{50}	630	2	Mount et al., 1997; ECHA
Scenedesmus subspicatus	72-hour EC_{50}	> 100* (growth rate)	1	ECHA

*NOEC = > 100 mg/L

Chronic Studies

In a fish early-life-stage test with the fathead minnow (*Pimephales promelas*), the 7-day NOEC was 500 mg/L (ECHA).

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (820 mg/L), *Daphnia* (660 mg/L) and algae (> 100 mg/L). Although a chronic study was conducted on fish that fulfils the requirements in the OECD TG 210, it is not considered adequate for deriving a PNEC because of the short duration of the test. On the basis of the short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported effect concentration of 100 mg/L for algae. The $PNEC_{water}$ is 1.0 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Potassium chloride dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of potassium chloride to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of potassium chloride is dominated by its water solubility. Sorption of potassium chloride should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, potassium chloride is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Potassium chloride is an inorganic salt that dissociates completely to potassium and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both potassium and chloride ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Potassium and chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Therefore, potassium chloride is not expected to bioaccumulate.

There are no adequate chronic aquatic toxicity studies available on potassium chloride. The acute $E(L)C_{50}$ values for potassium chloride are > 1 mg/L in fish, invertebrates and algae. Therefore, potassium chloride does not meet the screening criteria for toxicity.

The overall conclusion is that potassium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact

Wash with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Do not induce vomiting. Rinse mouth with water and then drink a small amount of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Firefighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: potassium oxides, hydrogen chloride, chlorine gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for potassium chloride.

Engineering Controls

Use in a well-ventilated area.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Potassium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Boyd, E.M., and Shanas, M.N. (1961). The acute oral toxicity of potassium chloride. Arch. Int. Pharmacodyn. Ther. 133: 275-283.

Brusick, D. (1988). Genotoxic effects in cultured mammalian cells produced by low pH treatment conditions and increased ion concentrations. Environ. Mutag. 8: 879-886.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

FDRL. (1975). Teratological evaluation of FDA 73-78 (KCl) in mice and rats. Final report prepared under DHEW. Contract No. FDA 223-74-2176 by Food and Drug Research Laboratories Inc. Waverly, New York.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Imai, S., Morimoto, J., Sekiya, N., Shima, M., Kiyozuka, Y., Nakamori, K., Tsubura, Y. (1986). Chronic toxicity test of KCl and NaCl in F344/Scl rats. J. Nara Med. Ass. 37:115-127 [in Japanese]; cited in OECD 2001a,b.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

Lina, B.A.R., and Kuijpers, M.H.M. (2004). Toxicity and carcinogenicity of acidogenic or alkalogenic diets in rats; effects of feeding NH_4Cl, $KHCO_3$ or KCl. Food Chem. Toxicol. 42: 135-153.

Mitchell, A.D., Rudd, C.J., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at SRI international. Env. Molecular Mutagenesis 12(13):37-101.

Mortelmans, K., Haworth, S., Lawlor, T., Speck, W., Tainer, B., Zeiger, E. (1986). Salmonella mutagenicity tests: II. Results from the testing of 270 chemicals. Env. Mutagenesis 8(7):1-119.

Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., and Evans, J.M. (1997). Statistical models to predict the toxicity of major ions to *Ceriodaphnia dubia, Daphnia magna* and *Pimephales promelas* (fathead minnows). Environ. Toxicol. Chem. 16: 2009-2019.

Myhr, B.C., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at Litton Bionetics, Inc. Env. Molecular Mutagenesis. 12(13):103-194.

OECD. (2001a). IUCLID Data Set for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

OECD. (2001b). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

PROPYLENE GLYCOL *n*-PROPYL ETHER

This dossier on propylene glycol *n*-propyl ether presents the most critical studies pertinent to the risk assessment of propylene glycol *n*-propyl ether in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 1-Propoxypropan-2-ol

CAS RN: 1569-01-3

Molecular formula: $C_6H_{14}O_2$

Molecular weight: 118.18

Synonyms: Propylene glycol *n*-propyl ether; 1-propoxypropan-2-ol; 1-propoxy-2-propanol; 2-propanol, 1-propoxy; propylene glycol propyl ether; propylene glycol-n-monopropyl ether; 2-propanol, propoxy-

SMILES: CCCOCC(C)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Propylene Glycol n-Propyl Ether

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless organic liquid with an ether-like odor.	2	ECHA
Melting point	ca. -70°C	2	ECHA
Boiling point	149.4°C	2	ECHA
Density	0.885 g/cm^3 @ 20°C	2	ECHA
Vapor pressure	2.85 mm Hg @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	0.621 @ 20°C (calculated)	2	ECHA
Water solubility	Completely miscible @ 30°C	2	ECHA
Flash point	46.4°C	2	ECHA

Property	Value	Klimisch score	Reference
Auto flammability	252°C	2	ECHA
Viscosity	2.389 mPa s @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is expected to biodegrade and not expected to bioaccumulate.

B. Biodegradation

Propylene glycol n-propyl ether is readily biodegradable. In an OECD 301 A test, degradation was 91.5% after 28 days (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption
No experimental data are available for propylene glycol n-propyl ether. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} of 0.621 is 4.944 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 2.375 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on propylene glycol n-propyl ether. Propylene glycol n-propyl ether is not expected to bioaccumulate based on a log K_{ow} of 0.621 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance is not significantly acutely toxic via oral exposure. It is not irritating nor is it considered a sensitizer. Repeat dose toxicity tests do not suggest a high degree of systemic toxicity.

B. Acute Toxicity

The oral LD_{50} of propylene glycol *n*-propyl ether in rats is >2,000 mg/kg (ECHA) [Kl. score = 2]. The inhalation 4-hour LC_{50} of propylene glycol *n*-propyl ether in rats is >1,725 ppm, the highest concentration attainable at room temperature (25°C) (ECHA) [Kl. score = 2].

The dermal LD_{50} of propylene glycol *n*-propyl ether in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 2].

C. Irritation

Application of 0.5 mL propylene glycol *n*-propyl ether to the skin of rabbits for 4 hours under occlusive conditions was not considered irritating. The mean of the 24, 48, and 72 hour scores were: 0.9 for erythema and 0.4 for edema (ECHA) [Kl. score = 2].

Instillation of 0.1 mL into the eyes of rabbits was considered irritating. The mean of the 24, 48, and 72 hour scores were: 0.9 for corneal opacity; 0.7 for iridial lesions; 0.9 for conjunctival redness; and 0.8 for chemosis (ECHA) [Kl. score = 2].

D. Sensitization

Propylene glycol *n*-propyl ether was not considered to be a skin sensitizer in a mouse local lymph node assay (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

Oral
No studies are available.

Inhalation
Male and female F344 rats (20/sex/dose) were exposed by inhalation to 0, 30, 100, or 300 ppm propylene glycol n-propyl ether 6 hours/day, 5 days/week for 14 weeks. At the end of the 14-week exposure period, 10 animals/sex/dose were sacrificed; the other 10 animals/sex/dose were given a 3-month recovery period. Clinical signs and the ophthalmic examination showed no treatment-related effects. The 300 ppm females had consistently lower body weight gain, except during the recovery period. Body weights, food and water consumption, and urinalysis were similar across groups. Total leucocyte count was decreased in the 30 and 300 ppm females and was associated with a decrease in lymphocytes in the 300 ppm females. There was no dose-response and the changes were not present following the 3-month recovery period. Organ weights, gross necropsy, and histopathology showed no treatment-related effects. The NOAEC for this study is 300 ppm (ECHA) [Kl. score 1].

Male and female SD rats (20/sex/dose) were exposed by inhalation to 0, 30, 100, or 300 ppm propylene glycol n-propyl ether 6 hours/day, 5 days/week for 14 weeks. At the end of the 14-week exposure period, 10 animals/sex/dose were sacrificed; the other 10 animals/sex/dose were given a 3-month recovery period. Clinical signs and the ophthalmic examination showed no treatment-related effects. The 100 ppm female rats had lower body weight gains for the first two weeks of the study. Body weights, food and water consumption, urinalysis, and hematology parameters were similar across groups. Organ weights, gross necropsy, and histopathology showed no treatment-related effects. The NOAEL for this study is 300 ppm (ECHA) [Kl. score 1].

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

The in vitro genotoxicity studies on propylene glycol *n*-propyl ether are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Propylene Glycol *n*-Propyl Ether

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Mammalian cell gene mutation (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberration (rat lymphocytes)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available.

G. Carcinogenicity

No studies are available.

H. Reproductive/Developmental Toxicity

A reproductive and developmental toxicity screening (OECD 421) study was conducted on propylene glycol n-propyl ether. Male and female Crl:CD(SD) rats were dosed by oral gavage with 0, 100, 300, or 1,000 mg/kg propylene glycol *n*-propyl ether. Transient, excess salivation was noted in many of the 1,000 ppm animals immediately after dosing; this was considered a local response to the dosing material and not toxicologically significant. Absolute and relative liver weights were increased in the male and female rats, with corresponding hepatocellular hypertrophy. Absolute and relative kidney weights were increased in the 1,000 males and females. There were hyaline droplets in the proximal tubules in the 1,000 ppm males, but no histopathologic changes seen in the 1,000 ppm females. At 1,000 mg/kg, there was a slight, treatment-related increase in post-implantation loss (11.26% vs 6.47% in controls), with a slight increase in gestation survival and a very slight decrease in litter size (14.0 vs 14.4 live pups/litter in control; not statistically significant but considered treatment-related). The mean litter size would have been lower (13.4%); one animal had a very large litter of 20 pups. One of the 1,000 mg/kg females had a difficult birth and retained placentae; this was considered an equivocal treatment-related effect. There was no indication of parental, reproductive, or developmental

toxicity at the lower two dose levels. The NOAEL for parental, reproductive, and developmental toxicity is 300 mg/kg-day (ECHA) [Kl. score = 1].

Pregnant female CD (SD) rats were dosed by exposed by inhalation to 0, 100, 750, or 1,500 ppm propylene glycol *n*-propyl ether 6 hours/day on GD 6-15. The 1,500 ppm females had eye irritation, significant reductions in body weight gain during GD 609, and reduced feed consumption during the exposure period. Corneal opacity was grossly observed in one 1,500 ppm dam; histologic examination showed corneal ulceration and associated keratitis, as well as corneal and scleral mineralization and scleral granulomas. The only developmental effect noted was poorly ossified hindlimb phalanges in the 1,500 ppm group. The NOAEL for maternal and developmental toxicity is 750 ppm (ECHA) [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for propylene glycol *n*-propyl ether follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A reproductive and developmental screening (OECD) study on propylene glycol n-propyl ether has been conducted by the oral route (ECHA). The NOAEL for parental, reproductive, and developmental toxicity is 300 mg/kg-day. This study is inadequate for an oral reference dose.

Two 14-week rat (different strains) inhalation studies have been conducted on propylene glycol n-propyl ether. The NOAEC for both studies is 300 ppm, based on decreased body weight gain in the female rats. The NOAEC of 300 ppm (1,474 mg/m^3) will be used for deriving an oral reference dose and drinking water guidance value for propylene glycol n-propyl ether.

It is assumed that absorption is 100% and the ventilation rate and body weight of a rat is 0.29 m^3/day (0.0121 m^3/hr) and 0.35 kg, respectively.

1,474 mg/m^3 x 0.0121 m^3/hr x 6 hr/day x 1/0.35 kg x 5 days/7 days = 218 mg/kg-day

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 3
UF_D (database uncertainty) = 1

Oral RfD = 218/(10 x 10 x 1 x31 x 1) = 218/300 = 0.7 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.7 x 70 x 0.1)/2 = 2.5 mg/L

B. Cancer

There are no carcinogenicity studies on propylene glycol *n*-propyl ether. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Propylene glycol *n*-propyl ether does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on propylene glycol n-propyl ether

Table 3: Acute Aquatic Toxicity Studies on Propylene Glycol *n*-Propyl Ether

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hr LC_{50}	>100	2	ECHA
Daphnia magna	48-hr EC_{50}	>100	2	ECHA

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pseudokirchnierella subcapitata	72-hr EC_{50}	3,440	1	ECHA

Chronic Studies
No data are available.

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for propylene glycol *n*-propyl ether follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (>100 mg/L), invertebrates (>100 mg/L), and algae (3,440 mg/L). On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported $E(L)C_{50}$ value of 100 mg/L for fish and *Daphnia*. The $PNEC_{water}$ is 1.0 mg/L.

PNEC soil
There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.03 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.05/1500) \times 1000 \times 1.0$
$= 0.03$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 2.38 \times 0.02$
$= 0.05$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for propylene glycol n-propyl ether based on the molecular connectivity index (MCI) is 2.38 L/kg (EPA, 2018).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Propylene glycol *n*-propyl ether is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a calculated log K_{ow} of 0.621, propylene glycol *n*-propyl ether does not meet the screening criteria for bioaccumulation.

There are no chronic aquatic toxicity studies on propylene glycol *n*-propyl ether. The acute $E(L)C_{50}$ values for fish, invertebrates, and algae are >1 mg/L. Thus, propylene glycol n-propyl ether does not meet the screening criteria for toxicity.

The overall conclusion is that propylene glycol *n*-propyl ether is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 3
Eye irritant Category 2

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. Remove contacts, if possible. If symptoms persist, seek medical attention.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
If swallowed, seek medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Specific Exposure Hazards
Burning produces harmful and toxic fumes. Combustion products may include: carbon monoxide, carbon dioxide.
Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus and protective clothing.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Spilled material may cause a slipping hazard.
Environmental Precautions
Prevent from entering sewers, waterways, or low areas.
Steps to be Taken if Material is Released or Spilled
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

D. Storage and Handling

General Handling
Do not swallow. Wash thoroughly after handling.
Storage
Keep container closed when not in use. Store in a dry place.

B. Fire Fighting Information

Extinguishing Media
Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Specific Exposure Hazards
Carbon oxides may be generated upon combustion. Substance is incompatible materials with strong oxidizing agents.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus for fire fighting if necessary.

C. Accidental Release Measures

Personal Precautions

Environmental Precautions

Steps to be Taken if Material is Released or Spilled
Do not allow release to open drains or surface water. Contain release with appropriate dikiing and barriers. Notify local authorities if substance migrates to public drains or surface water.

D. Storage And Handling

General Handling
Do not swallow. Wash thoroughly after handling.

Storage
Keep container closed when not in use. Store in a dry place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for propylene glycol *n*-propyl ether.

Engineering Controls
Use in a well-ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal Protection Equipment
Respiratory Protection:
Not normally needed. But if significant exposures are possible then the following respirator is recommended: organic vapour respirator with a dust/mist filter.

Hand Protection:
Chemical protective gloves

Skin Protection:
Normal work coveralls.

Eye protection:
Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions:

F. Transport Information

Australian Dangerous Goods

UN1993 (FLAMMABLE LIQUID, N.O.S.)
Class: 3
Packing Group: III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

SILICON DIOXIDE

This dossier on silicon dioxide presents the most critical studies pertinent to the risk assessment of silicon dioxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on synthetic amorphous silica and silicates (OECD 2004a,b), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Silicon dioxide

CAS RN: 112926-00-8

Molecular formula: $nSiO_2$

Molecular weight: 60.08

Synonyms: Silicon dioxide; synthetic amorphous silica; silica gel; precipitated silica, crystalline-free

SMILES: O=[Si]=O

Silicon dioxide is the IUPAC name for synthetic amorphous silica (SAS) [CAS No. 7631-86-9]; it can be produced by a "wet process" or by a "thermal or fumed process." Silica gel and precipitated silica, crystalline-free (CAS No. 112926-00-8) is a SAS prepared by the "wet process." Silica, amorphous, fumed, crystalline-free (CAS No. 112945-52-5) is a SAS prepared by flame hydrolysis.

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Silicon Dioxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Powder, granules, pellets	2	ECHA
Melting Point	1,713°C	2	ECHA

Property	Value	Klimisch score	Reference
Boiling Point	2.2 g/cm^3	2	ECHA
Water Solubility	76 – 128 mg/L* (slightly soluble)	1	ECHA

*Based on dissolved SiO_2.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Silicon oxides are the most abundant compounds in the earth's crust mass. Silicon dioxide (CAS No. 112926-00-8) released into the environment is expected to combine indistinguishably with the soil layer or sediment due to their chemical similarity with inorganic soil matter (OECD, 2004a).

Biodegradation is not applicable to silicon dioxide (CAS No. 112926-00-8). The bioavailable form of silicon dioxide (CAS No. 112926-00-8) is the dissolved form which exists exclusively monosilicic [$Si(OH)_4$] acid under environmental pH (OECD, 2004a). Although the water-soluble fraction of silicon dioxide (CAS No. 112926-00-8) acts as weak acid, pH changes are not likely to occur in the environment due to low aquatic releases and sufficient natural buffer capacities (OECD, 2004a).

Bioaccumulation of silicon dioxide (CAS No. 112926-00-8) is generally unlikely to occur. However, dissolved silica can be actively assimilated by some marine and terrestrial organisms as normal natural processes mainly related to structural function.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The oral bioavailability of silicon dioxide in animals and humans is low. Absorbed silicon dioxide is rapidly eliminated and there is no accumulation in the body. The bioavailablity of silicon dioxide by the inhalation route is low. While there is deposition in the lungs following inhalation exposure to silicon dioxide, it is rapidly eliminated. The acute toxicity of silicon dioxide is low by the oral, inhalation, and dermal routes. Silicon dioxide is not irritating to the skin and eyes. Repeated oral exposures to rodents showed no adverse effects. Repeated inhalation exposure to high respirable levels of silicon dioxide resulted in an inflammatory response in the respiratory tract and lungs, which was reversible following cessation of exposure. Silicon dioxide is not genotoxic. Although the study was of poor quality, there was no evidence of adverse effects on

reproduction in rats given silicon dioxide in the diet. Animal studies showed no adverse effects on fetal development from oral exposure to silicon dioxide.

B. Toxicokinetics/Metabolism

The oral bioavailability of silicon dioxide in animals and humans is low. Absorbed silicon dioxide is rapidly eliminated and there is no accumulation in the body. The bioavailablity of silicon dioxide by the inhalation route is low. While there is deposition in the lungs following inhalation exposure to silicon dioxide, it is rapidly eliminated (OECD, 2004a,b).

C. Acute Toxicity

The oral LD_{50} of silicon dioxide (CAS No. 112926-00-8) in rats from two different studies is >5,000 mg/kg (ECHA) [Kl. scores = 1].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112926-00-8) is >0.69 mg/L, which was the maximum technically attainable concentration. The mass median aerodynamic diameter (MMAD) was approximately 0.6 µm, and approximately 65% of the mass was <6 µm (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112945-52-5) is >2.08 mg/L. The mass median aerodynamic diameter (MMAD) was approximately 0.76 µm, and approximately 98-99.4% of the mass was <10 µm (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112945-52-5) from a nose-only exposure is >0.14 mg/L, which was the maximum technically attainable concentration. The mass median aerodynamic diameter (MMAD) was 3.2 µm, and 47-50% of the mass was <6 µm (ECHA) [Kl. score = 2].

The dermal LD_{50} in rabbits is >5,000 mg/kg (no deaths) (ECHA) [Kl. score = 2].

D. Irritation

Application of 0.5 g silicon dioxide (CAS No. 112926-00-8) to the skin of rabbits for 4 hours under occlusive conditions was not irritating. (ECHA) [Kl. score = 1].

Instillation of 0.1 g silicon dioxide (CAS No. 112926-00-8) to the eyes of rabbits was minimally irritating (ECHA) [Kl. score = 1].

E. Sensitization

No studies are available.

F. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given diets containing silicon dioxide (CAS No. 112926-00-8) for 90 days. The dietary concentrations as silica concentrations were 0, 0.4-0.7, 1.7-1.9, or 6.5-7.0% silica; this equates to 0, 300-330, 1,200-1,400, or 4,000-4,500 mg/kg CAS No. 112926-00-8. There were no treatment-related effects. The NOAEL is 4,000 to 4,500 mg/kg-day (ECHA). [Kl. score = 1]

Male and female CD rats were given diets containing silicon dioxide (CAS No. 112926-00-8) for 6 months. The estimated daily intakes were 0, 2,170, and 7,950 mg/kg-day for males, and 0, 2,420, and 8,980 mg/kg-day for females. There were no treatment-related effects. The NOAEL is 7,950 and 8,980 mg/kg-day for males and females, respectively (ECHA). [Kl. score = 1]

Male and female Fischer 344 rats were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 102 weeks. The dose levels were 0, 12,500, 25,000, and 50,000 ppm. There were no treatment-related effects on body weight gain, feed consumption, survival, or hematology parameters. Liver weights were lower (up to 15%) in the $\geq$25,000 ppm females from 12 to 24 months; a dose-related trend was not apparent. The NOAEL is 50,000 ppm. Using 0.05 as the fraction of body weight that rats consume per day as food (U.S. EPA), the NOAEL corresponds to 2,500 mg/kg-day (Takizawa *et al.*, 1988) [Kl. score = 2].

Male and female $B6C3F_1$ mice were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 93 weeks. The dose levels were 0, 12,500, 25,000, and 50,000 ppm. There were no treatment-related effects on survival or clinical signs. Body weight gain was lower in the 5% group from week 15 to week 50 for the males and from 30 to 50 for the females. Mean body weights for 5% group animals for the remainder of the study were similar to controls. The NOAEL is 50,000 ppm in the diet. Using 0.13 as the fraction of body weight that mice consume per day as food (U.S. EPA), the NOAELs corresponds to 6,500 mg/kg-day (Takizawa et al., 1988). [Kl. score = 2]

Inhalation

Male and female Wistar rats were exposed by inhalation to 0, 1, 6, or 30 mg/m^3 silicon dioxide (CAS No. 112945-52-5) 6 hours/day, 5 days/week for 13 weeks. There were no deaths during the study. Respiration rates were increased in a concentration-dependent manner. Body weight and body weight gain were unaffected in females, but were lower in the males with the 30 mg/m^3 groups significantly affected throughout the study. At $\geq$6 mg/m^3, there were hematological changes, increased lung weights, and histopathologic changes in the lungs (including collagen increase and sporadic focal fibrosis). At 1 mg/m^3, there was a slight, but fully reversible, pulmonary response

indicative of an inflammatory reaction. The NOAEC for this study is 1.3 mg/m^3 (ECHA) [Kl. score = 1].

Dermal
No adequate studies are available.

G. Genotoxicity

In Vitro Studies

The results of *in vitro* genotoxicity studies on silicon dioxide are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Silicon Dioxide

Test System	Test substance	Results*		Klimisch Score	Reference
		-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	CAS No. 112926-00-8	-	-	2	Prival *et al.* (1991)
Bacterial reverse mutation (*E. coli* strains)	CAS No. 112926-00-8	-	-	2	Prival *et al.* (1991)
Bacterial reverse mutation (*S. typhimurium* strains)	CAS No. 112945-52-5	-	-	1	ECHA
Mammalian cell gene mutation (CHO cells)	CAS No. 112945-52-5	-	-	1	ECHA
Chromosomal aberration (Human embryonic lung cells, WI-38)	CAS No. 112926-00-8	NA	-	2	ECHA
Chromosomal aberration (CHO cells)	CAS No. 112945-52-5	-	-	1	ECHA
Unscheduled DNA synthesis (primary rat hepatocytes)	CAS No. 112945-52-5	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable.

In Vivo Studies

Male F344 rats were exposed by inhalation to 0 or 50 mg/m^3 silicon dioxide (CAS No. 112945-52-5) 6 hours/day, 5 days/week for 13 weeks. When tested in a HPRT assay, there was no increase in mutation frequency in the alveolar Type II cells from exposed rats compared to controls (ECHA) [Kl. score = 2].

Male SD rats were given by oral gavage either a single dose of 0, 1,4, 14, or 140 mg/kg silicon dioxide (CAS No. 112926-00-8), or five consecutive daily doses of 0, 500, or 5,000 mg/kg silicon dioxide (CAS No. 112926-00-8). Chromosomal aberrations were not significantly increased in the treated animals compared to controls (ECHA) [Kl. score = 2].

In a dominant lethal mutation assay, male SD rats were given by oral gavage either a single dose of 0, 1,4, 14, or 140 mg/kg silicon dioxide (CAS No. 112926-00-8), or five consecutive daily doses of 0, 500, or 5,000 mg/kg silicon dioxide (CAS No. 112926-00-8). There was no indication of a mutagenic effect by silicon dioxide (CAS No. 112926-00-8) (ECHA) [Kl. score = 2].

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 102 weeks. The dose levels were 0, 12,500, 25,000, and 50,000 ppm. The incidence of tumors was similar between treated and control animals. The number of animals used in this study was small (Takizawa *et al.*, 1988). [Kl. score = 2]

Male and female B6C3F$_1$ mice were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 93 weeks. The incidence of tumors was similar between treated and control animals (Takizawa *et al.*, 1988). [Kl. score = 2].

I. Reproductive Toxicity

A one-generation reproductive toxicity study has been conducted on silicon dioxide (CAS No. 112945-52-5). Male and female Wistar rats were given diets containing 0 or 497 mg/kg-day (males) or 509 mg/kg-day (females). In the parental animals, there were no treatment-related effects on mortality, clinical symptoms, feed consumption, body weight gain, and measured hematology parameters. There was no reproductive or developmental toxicity (ECHA) [Kl. score = 3].

J. Developmental Toxicity

Pregnant female rats were given by oral gavage doses up to 1,350 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-15. There was no maternal or developmental toxicity.

The NOAEL for maternal and developmental toxicity is 1,350 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female mice were given by oral gavage doses up to 1,340 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,340 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female rabbits were given by oral gavage doses up to 1,600 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female Syrian hamsters were given by oral gavage up to 1,600 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-10. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for silicon dioxide (CAS No. 112945-00-8) follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

There were no adverse effects seen in rats or mice fed a diet containing up to 50,000 ppm silicon dioxide (CAS No. not stated) for 102 and 93 weeks, respectively (Takizawa *et al.*, 1988). The NOAELs for rats and mice were 2,500 and 6,500 mg/kg-day, respectively. The lowest NOAEL of 2,500 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1

UF_D (database uncertainty) = 1

Oral RfD = 2,500/(10 x 10 x 1 x 1 x 1) = 2,500/100 = 25 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (25 x 70 x 0.1)/2 = 88 mg/L

B. Cancer

Silicon dioxide was not carcinogenic to rats or mice in chronic dietary studies. Hence, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Silicon dioxide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Silicon dioxide has a low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on silicon dioxide.

Table 3: Acute Aquatic Toxicity Studies on Silicon Dioxide

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-h LL_0	10,000*	1	ECHA
Danio rerio	96-h LL_0	10,000	1	ECHA
Daphnia magna	48-h EL_{50}	>1,000**	2	ECHA
Daphnia magna	24-h EL_{50}	>10,000	2	ECHA

*Silica, amorphous, fumed, crystalline-free (CAS No. 112945-52-5)
**Mortality may have occurred may have occurred from physical effects of unfiltered medium.

Chronic Studies
No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for silicon dioxide follow the methodology discussed in DEWHA (2009).

PNEC water
Silicon dioxide is a solid in powder form, which is slightly soluble in water. Acute aquatic toxicity studies on fish and *Daphnia* using excess loadings of silicon dioxide showed no acute toxicity (Table 3). Physical effects of silicon dioxide on *Daphnia* were seen in tests using unfiltered test medium (OECD, 2004a,b; ECHA). Because of the physico-chemical properties of silicon dioxide, the $PNEC_{water}$ was not determined.

PNEC sediment
There are no toxicity data for sediment-dwelling organisms. The $PNEC_{sed}$ cannot be derived using the equilibrium partitioning method.

PNEC soil
There are no toxicity data for terrestrial or soil organisms. The $PNEC_{soil}$ cannot be derived using the equilibrium partitioning method.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Silicon dioxide (CAS No. 111945-00-8) released into the environment is expected to combine indistinguishably with the soil layer or sediment due to their chemical similarity with inorganic soil matter. Biodegradation is not applicable to silicon dioxide (CAS No. 112926-00-8). For the purposes of this PBT assessment, the persistent criteria is not considered applicable to silicon dioxide (CAS No. 112926-00-8).

Silicon dioxide (CAS No. 112926-00-8)is an inorganic substance that is a slightly soluble powder. Bioaccumulation of silicon dioxide (CAS No. 112926-00-8) is generally unlikely to occur, given its low bioavailability. However, dissolved silica can be actively assimilated by some marine and terrestrial organisms as normal natural processes mainly related to structural function. For the purposes of this PBT assessment, silicon dioxide (CAS No. 112926-00-8) does not meet the criteria for bioaccumulation.

The acute toxicity of the water-soluble fraction of silicon dioxide (CAS No. 112926-00-8) is >1 mg/L. Thus, it does not meet the criteria for toxicity.

The overall conclusion is that silicon dioxide (CAS No. 112926-00-8) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

No classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
No data are available.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage And Handling

General Handling
No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for silica gel (silicon dioxide, CAS No. 112926-00-8) in Australia is 10 mg/m^3 as an 8-hour TWA.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Use respiratory protection if airborne dust levels are expected to exceed the occupational exposure guidance value.

Hand Protection:
Use gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Silicon dioxide is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2004a). Screening Information Dataset (SIDS) Initial Assessment Report for Synthetic Amorphous Silica and Silicates: Silicon Dioxide (CAS No. 7631-86-9, 112945-52-5, 112926-00-8; Silicic Acid, Aluminum Sodium Salt (CAS No. 1344-00-9); Silicic Acid, Calcium Salt (CAS No. 1344-95-2), UNEP Publications.

OECD (2004b). IUCLID Data Set for Synthetic Amorphous Silica and Silicates: Silicon Dioxide (CAS No. 7631-86-9, 112945-52-5, 112926-00-8; Silicic Acid, Aluminum Sodium Salt (CAS No. 1344-00-9); Silicic Acid, Calcium Salt (CAS No. 1344-95-2), UNEP Publications.

Prival, M.J., Simmon, V.F., and Mortelmans, K.E. (1991). Bacterial mutagenicity testing of 49 food ingredients gives very few positive results. Mutat. Res. 260: 321-329.

Takizawa, Y., Hirasawa, F., Noritomi, E., Aida, M., Tsunoda, H., and Uesugi, S. (1988). Oral ingestion of syloid to mice and rats and its chronic toxicity and carcinogenicity. Acta Medica et Biologica 36: 27-56.

SODIUM BICARBONATE

This dossier on sodium bicarbonate presents the most critical studies pertinent to the risk assessment of sodium bicarbonate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydrogen carbonate

CAS RN: 144-55-8

Molecular formula: $CH_2O_3.Na$

Molecular weight: 84.01

Synonyms: Sodium bicarbonate; sodium hydrogen carbonate; baking soda; carbonic acid monosodium salt

SMILES: C(=O)(O)[O-].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Bicarbonate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, crystalline solid	1	ECHA
Melting Point	Decomposition @ 165°C	1	ECHA
Boiling Point	-	-	-
Density	>2.21 and ≤2.23 @ 20°C	1	ECHA
Vapor Pressure	66.9 Pa @ 20°C	2	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	93.4 g/L @ 20°C (pH 8.4)	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility and low vapor pressure, sodium bicarbonate will be found predominantly in the aquatic environment where it dissociates completely to sodium (Na^+) and bicarbonate (HCO_3^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

When bicarbonate is dissolved in water, a re-equilibration takes place according to the following equations:

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ pKa=10.33

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ pKa = 6.35

Only a small fraction of the dissolved CO_2 is present as H_2CO_3 (carbonic acid), the major part is present as CO_2. The amount of CO_2 in water is in equilibrium with the partial pressure of CO_2 in the atmosphere. The CO_2/ HCO_3^-/ CO_3^{2-} equilibria are the major buffer of the pH of freshwater.

Based on the above equations, CO_2 is the predominant species at a pH smaller than 6.35, while HCO_3^- is the predominant species at a pH in the range of 6.35-10.33 and CO_3^{2-} is the predominant species at a pH higher than 10.33.

Geochemical and biological processes dictate the natural concentration of CO_2/ HCO_3^-/ CO_3^2 in freshwater. For instance, a continuous source of carbonate in freshwater is from the deposition of carbonate ions from the dissolution of minerals. Carbon dioxide comes from the decay of organic matter in aquatic ecosystems. On the other hand, carbon dioxide dissolved in freshwater is utilized by plants in photosynthesis.

The addition of sodium bicarbonate to the aquatic environment could potentially increase the sodium and bicarbonate concentration. However, unlike sodium carbonate, sodium bicarbonate does not increase the pH of the water to high and/or lethal levels. Addition of bicarbonate to water will move the pH towards 8.34 (the mean of the two pKa values from the two above equations) (OECD, 2002).

Na^+ and HCO_3^- ions will not adsorb on particulate matter or surfaces and will not accumulate in living tissues.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium bicarbonate is not acutely toxic by the oral and inhalation routes. It is not irritating to the skin and eyes. No repeated dose toxicity studies have been conducted on sodium bicarbonate. However, it is not expected to be systemically available in the body from oral exposure due to its dissociation in bodily fluids and the neutralization of the bicarbonate ion in the stomach to CO_2. Sodium bicarbonate is not mutagenic or genotoxic. No developmental toxicity was seen in animal studies when given high dietary doses of sodium bicarbonate.

B. Toxicokinetics/Metabolism

Sodium bicarbonate will dissociate in bodily fluids to sodium (Na^+) and bicarbonate (CO_3^-) ions. The oral uptake of sodium bicarbonate would lead to neutralization of bicarbonate in the stomach by the gastric acids, resulting in carbon dioxide (CO_2) formation (see equation below). It is unlikely that an oral uptake of sodium bicarbonate would disrupt the acid-base balance of the body because CO_2 formation in the stomach would alleviate the high amounts of bicarbonate that would be present in the stomach from an acute exposure. The equation that describes this reaction is:

$HCO_3^- + H^+ \leftrightarrow H_2CO_3 \leftrightarrow CO_2 + H_2O$

The bicarbonate is the principal extracellular buffer in the blood and interstitial fluids (Ganong, 1995).

C. Acute Toxicity

The oral LD_{50} values of sodium bicarbonate in rats from two different studies are >4,000 and 7,334 mg/kg (ECHA) [Kl. scores = 1]. Other studies have also reported similar oral LD_{50} values in rats (ECHA).

The inhalation 4.5-hour LC_{50} in rats is >4.74 mg/L. There was no mortality, and the mass median aerodynamic diameter (MMAD) was 2.8 µm (ECHA). [Kl. score = 1]

In humans, acute oral ingestion of sodium bicarbonate may result in a ruptured stomach due to excessive gas development. Acute or chronic excessive oral ingestion may cause metabolic alkalosis, cyanosis, and hypernatremia. These conditions are reversible and will not cause adverse effects (OECD, 2002).

D. Irritation

Application of 0.5 g sodium bicarbonate to the skin of rabbits for 4 hours under semiocclusive conditions was slightly irritating. The Primary Dermal Irritation Index was 0.3. The mean of the 24, 48, and 72 hour scores for erythema and edema were 0.06 and 0.00, respectively (ECHA) [Kl. score = 1]

Instillation of 0.05 – 0.07 ml of sodium bicarbonate to the eyes of rabbits was slightly irritating. The mean of the 24, 48, and 72 hour scores were: 0 for corneal opacity; 0 for iridial lesions; 0.33 for conjunctival redness; and 0 for chemosis (ECHA). [Kl. score = 1]

E. Sensitization

No studies are available.

F. Repeated Dose Toxicity

No studies are available.

G. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on sodium bicarbonate are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Sodium Bicarbonate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Ishidate *et al.*, 1984; OECD, 2002
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	De Flora *et al.*, 1984; OECD, 2002
Chromosomal aberration (Chinese hamster fibroblasts)	-	-	2	Ishidate *et al.*, 1984; OECD, 2002

*+, positive; -, negative

In vivo Studies

No studies are available.

H. Carcinogenicity

Male F344 rats were given in their feed 0 or 0.64% sodium bicarbonate for 104 weeks. The survival rat was 84% and 73% for the treated and control animals, respectively. There was no significant difference in the incidence of bladder tumors between the treated and control groups (OECD, 2002). [Kl. score = 2]

I. Reproductive Toxicity

No studies are available.

J. Developmental Toxicity

Pregnant female Wistar rats were given by oral gavage 0, 3.4, 15.8, 73.3, or 340 mg/kg sodium bicarbonate on gestational days 6 to 15. There was no maternal or developmental toxicity, with the NOAELS being 340 mg/kg-day, the highest doses tested (ECHA). [Kl. score = 2]

Pregnant female CD-1 mice were given by oral gavage 0, 5.8, 27, 125, or 580 mg/kg sodium bicarbonate on gestational days 6 to 15. There was no maternal or developmental toxicity, with the NOAELS being 580 mg/kg-day, the highest doses tested (ECHA). [Kl. score = 2]

Pregnant female Dutch rabbits were given by oral gavage 0, 3.3, 15.3, 71.2, or 330 mg/kg sodium bicarbonate on gestational days 6 to 18. There was no maternal or developmental toxicity, with the NOAELS being 330 mg/kg-day, the highest doses tested (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

There are no adequate repeated dose toxicity studies conducted on sodium bicarbonate by any route of exposure. A limited carcinogenicity study showed no increase in bladder tumors in rats given sodium bicarbonate in their diet. Developmental toxicity studies conducted by the oral route in three animals species showed no developmental effects at the highest doses tested. Sodium bicarbonate dissociates to sodium and bicarbonate ions in bodily fluids, and significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms.

Sodium bicarbonate is used in many countries (*e.g,.* U.S. and EU) as a food additive. It is regarded as a 'Generally Recognized as Safe' (GRAS) substance in food with no limitation other than current good manufacturing practice (OECD, 2002).

Thus, a toxicological reference value was not derived for sodium bicarbonate.

The Australian drinking water guideline values for sodium (180 mg/L, aesthetic) and pH of 6.5 to 8.5 may be applicable (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium bicarbonate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium bicarbonate is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies on sodium bicarbonate.

Table 3: Acute Aquatic Toxicity Studies on Sodium Bicarbonate

Test Species	Endpoint	Results (g/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LC_{50}	7,700	1	ECHA
Lepomis macrochirus	96-h LC_{50}	7,100	1	ECHA
Daphnia magna	48-h EC_{50}	4,100	1	ECHA
Daphnia magna	48-h EC_{50}	1,640	1	ECHA
Ceriodaphnia dubia	48-h EC_{50}	1,020	2	ECHA

Chronic Studies
The NOEC from a 21-day *Daphnia* reproduction study is >576 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

The 48-h LC_{50} and NOEC from an acute honeybee test on sodium bicarbonate was >24 and 24 µg/bee, respectively (ECHA).

D. Calculation of PNEC

The acute $E(L)C_{50}$ values to fish and invertebrates are >1,000 mg/L, and the NOEC from a chronic Daphnia study is >576 mg/L. Both sodium and bicarbonate ions are ubiquitous in the environment. UNEP (1995) reported that the 10th and 90th percentiles of bicarbonate ion present in 77 rivers were 20 and 195 mg/L, respectively; for sodium, the 10th and 90th percentiles in 75 rivers were 1.5 and 68 mg/L, respectively. OECD (2002) concluded: "Because the natural pH, bicarbonate and also the sodium concentration (and their fluctuations in time) varies significantly between aquatic ecosystems, it is not considered useful to derive a generic PNEC or $PNEC_{added}$. To assess the potential environmental effect of a sodium bicarbonate discharge, the increase in sodium, bicarbonate and pH should be compared with the natural values and their fluctuations and based on this comparison it should be assessed if the anthropogenic addition is acceptable."

Based on the information above, PNEC values for freshwater, sediment, and soil were not derived for sodium bicarbonate.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium bicarbonate is an organic salt that dissociates completely to sodium and bicarbonate

ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and bicarbonate ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria is not considered applicable to this inorganic salt.

Sodium and bicarbonate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. Therefore, sodium bicarbonate is not expected to bioaccumulate.

The NOEC for sodium bicarbonate from a chronic *Daphnia* study is >0.1 mg/L. The acute $E(L)C_{50}$ values for sodium bicarbonate are >1 mg/L in fish and invertebrates. Thus, sodium bicarbonate does not meet the screening criteria for toxicity.

The overall conclusion is that sodium bicarbonate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Contact
Wash with soap and water. Get medical attention if irritation persists.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Do not induce vomiting. Slowly dilute with 1-2 glasses of water or milk and seek medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Decomposition in fire may produce toxic gases. Combustion products include: carbon dioxide, carbon monoxide,

Special Protective Equipment for Firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage And Handling

General Handling
Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust.

Storage
Store away from acids. Store in a cool, dry location. Product has a shelf life of 36 months.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia does not have an occupational exposure standard for sodium bicarbonate.

Engineering Controls
Use in a well ventilated area. Localized ventilation should be used to control dust levels.

Personal Protection Equipment
If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection: Dust/mist respirator. (N95, P2/P3)

Hand Protection: Normal work gloves.

Skin Protection: Normal work coveralls.

Eye protection: Dust proof coveralls.

Other Precautions: Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium bicarbonate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

De Flora, S., Zanacchi, P., Camoirano, A., Bennicelli, C., and Badolati, G.S. (1984). Genotoxicity activity and potency of 135 compounds in the Ames reversion test in a bacterial DNA-repair test. Mutat. Res. 133: 161-198.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Harper DD1, Farag AM, Skaar D. (2013). Acute toxicity of sodium bicarbonate, a major component of coal bed natural gas produced waters, to 13 aquatic species as defined in the laboratory. Environ Toxicol Chem. 2014 Mar;33(3):525-31.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Ishidate, M., Sofuni, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., and Matsuoka, A. (1984). Primary mutagenicity screening of food additives currently used in Japan. Fd. Cosmet. Toxicol. 22: 623-636.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2002). SIDS Initial Assessment Report (SIAR) and IUCLID Data Set on Sodium bicarbonate (CAS No. 144-55-8), UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/sodbicarb.pdf.

UNEP (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002.

SODIUM BISULFITE

This dossier on sodium bisulfite presents the most critical studies pertinent to the risk assessment of sodium bisulfite used in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained mainly from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydrogen sulfite

CAS RN: 7631-90-5

Molecular formula: $NaHSO_3$

Molecular weight: 104.1

Synonyms: Sodium bisulfite; sodium hydrogen sulfite; sodium hydrogensulfite; monosodium sulfite; sodium sulfhydrate; hydrogen sodium sulfite; sulfurous acid, monosodium salt

SMILES: OS(=O)[O].[Na]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of Sodium Bisulfite

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, crystalline, solid	-	HSDB
Melting Point	Decomposes	-	HSDB
Density	1.348 g/cm^3	1	ECHA
Vapor Pressure	Not applicable	-	-
Partition Coefficient (log K_{ow})	Not applicable	-	-

Property	Value	Klimisch score	Reference
Water Solubility	Very soluble	2	ECHA

Sodium bisulfite is a weak acid with a pK_a of 6.97. Its conjugate base is the sulfite ion (SO_3^{2-}).

$NaHSO_3 \leftrightarrow Na^+ + HSO_3^-$

$HSO_3^- \leftrightarrow H^+ + SO_3^{2-}$

At neutral pH, a mixture of 50% sulfite (SO_3^{2-}) and 50% bisulfite (HSO_3^{2-}) is present.

In surface waters, sulfite is oxidized to sulfate either catalytically by air oxygen or by microbial action (OECD, 2008). The presence of cations like iron, copper or manganese in the environment accelerates the oxidation rate significantly.

Dissociation of sodium bisulfite in aqueous solutions can also liberate sulfur dioxide (SO_2), which is a gas.

III. ENVIRONMENTAL FATE PROPERTIES

At environmental pHs, sodium bisulfite dissociates in water to form sodium (Na^+) ions, bisulfite ions (HSO_3^-), sulfite (SO_2^{3-}) ions, and sulfur dioxide (SO_2) which is a gas.

Sodium bisulfite is not expected to bioaccumulate in the environment because of its dissociation to ionic species and a gas. Furthermore, sulfite will oxidize to sulfate, which is ubiquitous in the environment.

Sodium bisulfite and its dissociated species are expected to have a low potential to adsorb to soil and sediment.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Limited toxicity data are available on sodium bisulfite; therefore, structural analogues have been used to read-across to sodium bisulfite. Sodium sulfite has low acute toxicity by the oral, inhalation, and dermal routes. Sodium sulfite is minimally irritating to the skin and slightly irritating to the eyes. Sodium sulfite is not a skin sensitizer. No systemic toxicity was seen in rats when given sodium metabisulfite in their diet over a lifetime. There were, however, indications of stomach lesions as a result of localized

irritation from the ingestion of sodium metabisulfite. Sodium bisulfite is not expected to be genotoxic. No reproductive or developmental toxicity was observed in any of the animal studies on sodium bisulfite or its structural analogues.

B. Acute Toxicity

No acute toxicity studies are available for sodium bisulfite.

The oral LD_{50} value in rats for sodium sulfite is 2,610 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} values in rats for sodium metabisulfite are 1,420 mg/kg (males), 1,630 mg/kg (females), and 1,540 mg/kg (combined sexes) (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats for sodium sulfite is >5.5 mg/L (ECHA). [Kl. score = 2]

The dermal LD_{50} in rats for sodium sulfite is >2,000 mg/kg (ECHA). [Kl. score = 2]

C. Irritation

No studies are available on sodium bisulfite.

Application of 0.5 mL of sodium sulfite to the skin of rabbits for 4 hours under occlusive conditions was minimally irritating. The mean of the 24, 48, and 72 scores were: 0.5 for erythema and 0.0 for edema (ECHA). [Kl. score = 2]

Instillation of 0.1 mL of sodium sulfite (with 0.5% cobalt sulfate) into the eyes of rabbits produced slight irritation. The mean of the 24, 48, and 72 hour scores are as follows: 0.5 for conjunctival redness; 0.5 for conjunctival chemosis; 0.0 for corneal lesions; and 0.0 for iridial lesions (ECHA). [Kl. score = 2]

D. Sensitization

No studies are available on sodium bisulfite.

Sodium bisulfite was not considered a skin sensitizer in a mouse local lymph node assay (ECHA). [K. score = 1]

E. Repeated Dose Toxicity

<u>Oral</u>
No studies are available on sodium bisulfite.

A study is available on sodium metabisulfite. Sodium metabisulfite dissociates in water to form sodium (Na^+) ions, disulfite ($S_2O_5^{2-}$) ions, and sulfur dioxide (SO_2). The disulfite

ions can form bisulfite (HSO_3^-) and sulfite ions (SO_2^{3-}); at neutral pH, a mixture of 50% sulfite (SO_3^{2-}) and 50% bisulfite (HSO_3^{2-}) is present.

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of sulfite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulfite from the feed containing sodium metabisulfite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. Addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The general condition of the rats was good during the first 72 weeks in the F_0 generation, as well as the other two generations. After 72 weeks, there was a rapid increase in mortality in all groups. Survival in the treated groups were generally higher than the controls, except for the 2% F_1 males; no deaths occurred in the 2% F_2 females. A marginal reduction in body weight gain was observed in the 2% dose group (both sexes) in the F_1 and F_2 generations. Feed consumption was similar between treated and control groups. There were no changes in hematology and clinical chemistry parameters and urinalysis that were considered toxicologically significant. The $\geq$1% dietary groups had occult blood in their feces. Relative kidney weights were increased in the 2% F_2 females, but there were no pathological changes noted in the kidneys from this group. Hyperplastic changes in the fore- and glandular stomachs were noted in the $\geq$1% groups in all three generations. Some slight alterations were also noted in stomachs of the 0.5% F_2 rats. The NOAEL for systemic toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g. The histopathologic effects on the stomach and the occult blood in feces are considered to be the result of localized irritation (a site-of-contact effect) from the ingestion of sodium metabisulfite (Til et al., 1972; ECHA). [Kl. score = 2]

Inhalation

No studies on sodium bisulfite were located.

Dermal

No studies on sodium bisulfite were located.

G. Genotoxicity

In Vitro Studies

No *in vitro* genotoxicity studies were located for sodium bisulfite. Table 2 presents the findings from *in vitro* genotoxicity studies conducted on structural analogues of sodium bisulfite.

Table 2: *In Vitro* Genotoxicity Studies on Structural Analogues to Sodium Bisulfite

Test System	Test Substance	Results*		Klimisch Score	Reference
		-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	Sodium metabisulfite	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	Potassium metabisulfite	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	Potassium metabisulfite	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	Sodium metabisulfite	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	Sodium metabisulfite	-	-	2	ECHA
Chromosomal aberration (human lymphocytes)	Sodium metabisulfite	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

Sodium bisulfite did not show a mutagenic response in a rat dominant lethal assay when given in feed at doses of 0, 4.5, 15, or 45 mg/kg-day (ECHA). [Kl. score = 2]

Sodium sulfite was not genotoxic in a bone marrow micronucleus test in rats. Male NMRI rats were given a single subcutaneous injection of 0, 250, 500, or 1,000 mg/kg sodium sulfite (ECHA). [Kl. score = 1]

H. Carcinogenicity

No studies are available on sodium bisulfite.

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. There was no increased incidence of tumors in the treated groups compared to the controls (Til et al., 1972). [Kl. score = 2]

Male and female ICR/JCL mice were given in their drinking water 0, 1, or 2% potassium metabisulfite for two years. There was no increased incidence of tumors in the treated groups compared to the controls (Tanaka et al., 1979). [Kl. score = 2]

No inhalation or dermal carcinogenicity studies were located.

I. Reproductive Toxicity

No studies are available on sodium bisulfite.

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of sulfite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulfite from the feed containing sodium metabisulfite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. Addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The effects other than reproductive and developmental toxicity are discussed above in the Repeated Dose Toxicity section. There were no treatment-related effects on female fertility, the number of young per litter, or birth weight or mortality of the offspring. The number of F_{2a} pups was significantly reduced in the $\geq$0.5% groups during the first breeding cycle, but there was no dose-response and the reduction did not occur during the second breeding cycle. Slight growth retardation was observed in the F_1 and F_2 generation rats both before and after weaning. The NOAEL for reproductive toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g (Til et al., 1972; ECHA). [Kl. score = 2]

Male and female rats were given sodium metabisulfite in their drinking water for up to 2.5 years and in three successive generations. The doses were 375 and 750 ppm as sulfur dioxide (SO_2). There was no evidence of systemic toxicity in either dose group. The number of offspring of either the F_1 and F_2 generation and the proportion surviving to the end of lactation were similar between treated and control groups. The NOAEL for reproductive toxicity is 750 ppm (as SO_2) in drinking water. Assuming an average rat body weight of 400 g and a daily water intake of 28 mL, 750 ppm (as SO_2) corresponds to 53 mg/kg-day sodium metabisulfite (Lockett and Natoff, 1960; ECHA). [Kl. score = 2]

J. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with up to 110 mg/kg-day sodium bisulfite during GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity for this study is 110 mg/kg-day (ECHA). [Kl. score = 2]

Pregnant female CD-1 mice were dosed by oral gavage with up to 150 mg/kg-day sodium bisulfite during GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity for this study is 150 mg/kg-day (ECHA). [Kl. score = 2]

Pregnant female Dutch-belted were dosed by oral gavage with up to 100 mg/kg-day sodium bisulfite during GD 6-18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity for this study is 100 mg/kg-day (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for sodium metabisulfite follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>

No repeated dose toxicity studies have been conducted on sodium bisulfite. In a study conducted on sodium metabisulfite, there was no evidence of systemic toxicity in rats fed up to 2% for two years (Til et al., 1972). The NOAEL for this study is 2% or 955 mg/kg-day.

Using the molecular weights of sodium metabisulfite (190.1 g/mol) and sodium bisulfite (104.1 g/mol), the NOAEL of 955 mg/kg-day for sodium metabisulfite is converted to 523 mg/kg-day for sodium bisulfite. The NOAEL of 523 mg/kg-day will be used for determining the oral reference dose (RfD) and the drinking water guidance value for sodium bisulfite.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 523/(10 x 10 x 1 x 1 x 1) = 523/100 = 5 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (5 x 70 x 0.1)/2 = 18 mg/L

The Australian drinking water guidance value for sodium is 180 mg/L based on aesthetics (ADWG, 2011).

B. Cancer

There are no carcinogenicity studies on sodium bisulfite. No carcinogenic effects were reported for sodium metabisulfite in rat and mouse chronic studies. As there is inadequate evidence for the carcinogenicity in humans of sulfur dioxide, sulfites, bisulfites and metabisulfites (PubChem 2020) a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium bisulfite does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

No aquatic toxicity studies have been conducted on sodium bisulfite. Other inorganic sulfite compounds show low to moderate toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

No acute aquatic studies are available on sodium bisulfite; however, studies are available on other inorganic sulfite compounds. The studies on these inorganic sulfite compounds can used to read-across to sodium bisulfite since sulfite ions are formed in water upon dissociation of sodium bisulfite. Table 3 lists the results of acute aquatic toxicity studies on the structural analogues of sodium bisulfite.

Table 3: Acute Aquatic Toxicity Studies on the Structural Analogues of Sodium Bisulfite

Test Species	Test Substance	Endpoint	Results (mg/L)	Klimisch score	Reference
Leuciscus idus	Potassium sulfite	96-hr LC_{50}	316	2	ECHA
Salmo gairdneri	Sodium pyrosulfite	96-hr LC_{50}	147-215 (177.8*)	2	ECHA
Brachydanio rerio	Potassium metabisulfite	96-hr LC_{50}	464-1,000 (681.2*)	1	ECHA
Daphnia magna	Sodium disulfite	48-hr EC_{50}	88.8	2	ECHA
S. subspicatus	Sodium disulfite	96-hr EC_{50} 72-hr EC_{10}	43.9 33.3	2	ECHA

*Geometric mean.

Chronic Studies

No chronic studies are available on sodium bisulfite; however, studies are available on sodium sulfite. Table 4 lists the results of chronic aquatic toxicity studies conducted on sodium sulfite.

Table 4: Chronic Aquatic Toxicity Studies on Sodium Sulfite (CAS No. 7757-83-7)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	34-d NOEC	>316	1	ECHA
Daphnia magna	21-d NOEC	>10	2	ECHA

B. Terrestrial Toxicity

No studies were located.

C. Calculation of PNEC

The PNEC calculations for sodium bisulfite follow the methodology discussed in DEWHA (2009).

PNEC water

No studies have been conducted on sodium bisulfite; however, the results from studies conducted on other inorganic sulphite compounds can be used to read-across to sodium bisulfite. Hence, experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (177.8 mg/L for sodium pyrosulfite), invertebrates (88.8 mg/L for sodium sulfite), and algae (43.9 mg/L for sodium disulfite).

Results from chronic studies on sodium sulfite are also available for all three trophic levels, with the lowest NOEC being 10 mg/L for invertebrates. Using the molecular weights of sodium sulfite (126 g/mol) and sodium bisulfite (104.1 g/mol, the NOEC of 10 mg/L for sodium sulfite is converted to 8.3 mg/L. On the basis that the data consist of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 8.3 mg/L for invertebrates. The $PNEC_{water}$ is 0.8 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. Sodium bisulfite dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium bisulfite. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of sodium bisulfite to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. Sodium bisulfite dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium bisulfite. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, no adsorption of sodium bisulfite to soil is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium bisulfite is an inorganic compound that dissociates completely to ionic species and sulfur dioxide gas. Biodegradation is not applicable to these compounds. For the purposes of this PBT assessment, the persistent criterion is not considered applicable to sodium bisulfite or its dissociated compounds.

Sodium bisulfite is not expected to bioaccumulate because its dissociated species are inorganic ions and a gas.

There are no aquatic toxicity data on sodium bisulfite. The lowest NOEC from chronic aquatic toxicity studies on sodium sulfite, a structural analogue of sodium bisulfite, is >0.1 mg/L. Thus, sodium bisulfite is not expected to meet the criteria for toxicity.

The overall conclusion is that sodium bisulfite is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Aquatic Acute Category 3
Harmful if swallowed

B. Labelling

Warning

C. Pictogram



(Pubmed 2020)

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS) [for a solution of sodium bisulfite]

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
When contacted by water, sodium bisulfite releases sulfur dioxide (SO_2), a poisonous gas. In the case of fire, the following may be liberated: Sulfur oxides and sulfur dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Pick up with absorbent material. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
No special measures necessary provided product is used correctly.

Other Handling Precautions
Avoid eye and skin contact.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for sodium bisulfite in Australia is 5 mg/m^3 as an 8-hr TWA.

Engineering Controls
None

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium bisulfite is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

de Giovanni-Donnelly, R. (1985). The mutagenicity of sodium bisulfite on based-substitution strains of *S. typhimurium*. Teratogen. Carcinogen. Mutagen. 5: 195-203.

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HSDB. Hazardous Substance Database: https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm.

Ishidate, M., Sofumi, T., Yoshikawa, K., Hayashi, M., Nohmi, T., Sawada, M., and Mastuoka, A. (1984). Primary mutagenicity screening of food additives currently used in Japan. Fd. Chem. Toxicol. 22: 623-636.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2001). OECDS-SIDS: Disodium disulphite (CAS No. 7657-4). UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/DISODIUM.pdf.

OECD (2008). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium Sulfite (CAS No. 7757-83-7). Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=AF456240-42B5-4118-8E97-4FE480D85FB9.

Lockett, M.F., and Natoff, I.L. (1960). A study of the toxicity of sulfite. 1. J. Pharm. Pharmacol. 12: 488-496.

Pagano, D.A., and Zeiger, E. (1987). Condition affecting the mutagenicity of sodium bisulfite in *S. typhimurium*. Mutat. Res. 179: 159-166.

Pagano, D.A., Zeiger, E., and Stack, A. (1990). Autooxidation and mutagenicity of sodium bisulfite. Mutat. Res. 228: 89-96.

Renner, H.W., and Wever, J. (1983). Attempts to induce cytogenetic effects with sulphite in sulphite oxidase-deficient Chinese hamsters and mice. Fd. Chem. Toxicol. 21: 123-127.

Tanaka, T., Fujii, M., Mori, H., and Hirono, I. (1979) Carcinogenicity test of potassium metabisulfite in mice. Ecotoxicol. Environ. Safety 3: 451-453.

Til, H.P., Feron, V.P., de Groot, A.P. (1972). The toxicity of sulphite. I. Long-term feeding and multigeneration studies in rats. Fd. Cosmet. Toxicol. 10: 291-310.

SODIUM CARBONATE

This dossier on sodium carbonate presents the most critical studies pertinent to the risk assessment of sodium carbonate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on sodium carbonate (OECD, 2002a, b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): disodium carbonate

CAS RN: 497-19-8

Molecular formula: $CH_2O_3.2Na$

Molecular weight: 106

Synonyms: sodium carbonate; disodium carbonate; carbonic acid, disodium salt; bisodium carbonate; soda ash, calcined soda

SMILES: C(=O)([O-])[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Sodium Carbonate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid; white powder	1	ECHA
Melting Point	851°C	2	ECHA
Boiling Point	No data	-	-
Density	>2.52 and <2.53 (20°C)	1	ECHA
Vapour Pressure	No data	-	-
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	404 g/L* [soluble]	2	ECHA
pH	ca 11.5**	2	ECHA
Flammability	No	1	ECHA

*GLP-compliant study. The water solubility was overestimated, possibly due to the high temperature (during dissolution) or due to gel formation.

**pH value from water solubility test.

Aqueous solutions are strongly alkaline. At 25°C, the pH of 1, 5 and 10 wt% sodium carbonate solutions are 11.37, 11.58, and 11.70, respectively (Eggeman, 2001).

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility and low vapour pressure, sodium carbonate will be found predominantly in the aquatic environment where it dissociates completely to sodium (Na^+) and carbonate (CO_3^{2-}) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

Addition of sodium carbonate to an aquatic ecosystem will result in an increase in alkalinity and a tendency to increase the pH. The carbonate ions will react with water, forming bicarbonate (HCO_3^-) and hydroxide (OH^-) ions until an equilibrium is reached. A re-equilibration takes place when carbonate (CO_3^{2-}) is dissolved in water according to the following equations:

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ pKa=10.33

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ pKa = 6.35

Only a small fraction of the dissolved CO_2 is present as H_2CO_3 (carbonic acid), the major part is present as CO_2. The amount of CO_2 in water is in equilibrium with the partial pressure of CO_2 in the atmosphere. The CO_2/ HCO_3^-/ CO_3^{2-} equilibria are the major buffer of the pH of freshwater.

Based on the above equations, CO_2 is the predominant species at a pH smaller than 6.35, while HCO_3^- is the predominant species at a pH in the range of 6.35-10.33 and CO_3^{2-} is the predominant species at a pH higher than 10.33.

A release of sodium carbonate into the aquatic environment from the use of sodium carbonate could potentially increase the sodium concentration and the pH in the aquatic environment. Table 2 shows the concentration of sodium carbonate needed to increase the pH to values of 9.0, 10.0, and 11.0.

Table 2: Sodium Carbonate Concentration (mg/L) Needed to Increase pH (DeGroot et al., 2002; taken from OECD, 2002b).

Buffer capacity*	Final pH**		
	9.0	10.0	11.0
0 mg/L HCO_3^- (distilled water)	11.1 (0.6)	16 (6.1)	603 (61)
20 mg/L HCO_3^- (10th percentile of 77 rivers)	2.7 (21)	32 (26)	766 (81)
106 mg/L HCO_3^- (mean value of 77 rivers)	9.7 (107)	102 (112)	1467 (167)
195 mg/L HCO_3^- (90th percentile of 77 rivers)	17 (196)	175 (201)	2192 (256)

*The initial pH of a bicarbonate solution with a concentration of 20-195 mg/L is 8.3 (calculated).

**The final concentration of bicarbonate is given in parentheses.

Na^+ and CO_3^{2-} ions will not adsorb on particulate matter or surfaces and will not accumulate in living tissues (OECD 2002b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

There are limited toxicity data on sodium carbonate. It has a low order of acute toxicity by the oral, dermal, and inhalation routes. It is not a skin irritant, but it is an eye irritant. Sodium carbonate is not expected to be systemically available in the body from oral exposure due to its dissociation in bodily fluids and the neutralisation of the carbonate ion in the stomach. No developmental toxicity was seen in studies with rats, mice, or rabbits.

B. Toxicokinetics and Metabolism

Sodium carbonate will dissociate in bodily fluids into sodium (Na^+) and carbonate (CO_3^{2-}) ions. The oral uptake of sodium carbonate would lead to neutralisation of carbonate in the stomach by the gastric acids which would lead to bicarbonate and/or carbon dioxide (CO_2) formation. It is unlikely that an oral uptake of sodium carbonate would disrupt the acid-base balance of the body because CO_2 formation in the stomach would alleviate the high amounts of carbonate that would be present in the stomach from an acute exposure. However, excessively large doses may be corrosive to the gastro-intestinal tract. The equation that describes the bicarbonate dissociation reaction is:

$HCO_3^- + H^+ \leftrightarrow H_2CO_3 \leftrightarrow CO_2 + H_2O$

C. Acute Toxicity

An acute oral LD_{50} of sodium carbonate monohydrate in rats is 2,800 mg/kg, and the acute dermal LD_{50} in rabbits is >2,000 mg/kg (OECD, 2002a,b; ECHA). [Kl. scores = 1]

An acute inhalation toxicity study was conducted on an aerosol of sodium combustion products, which contain predominantly sodium carbonate. The 2-hour inhalation LC_{50} values for this aerosol to guinea pigs, mice and rats were 800, 1,200 and 2,300 mg/m^3, respectively. The median aerodynamic diameter of the aerosol was 0.77 $\pm$ 2.1μm (OECD, 2002a, b; ECHA). [Kl. score = 1]

D. Irritation

As reviewed in the OECD-SIDS documents (OECD, 2002a,b), skin irritation studies in laboratory animals and human volunteers with sodium carbonate either as a 50% solution or as a solid showed slight to no skin irritation.

Sodium carbonate is an eye irritant (OECD, 2002a,b; ECHA). A dose of 0.1 ml sodium carbonate monohydrate was irritating to the eyes of rabbits and, in another study, 0.1 ml of sodium carbonate (anhydrous) was highly irritating to rabbit eyes. However, 0.1 g sodium carbonate (anhydrous) was found not to be an eye irritant. [Kl scores of 1, 2, 1, respectively]

E. Sensitisation

No studies were identified.

F. Repeated Dose Toxicity

No studies were identified by the oral, inhalation or dermal routes.

G. Genotoxicity

In Vitro Studies

Sodium carbonate did not induce primary DNA damage in an *E. coli* chromotest (Olivier and Marzin, 1987; OECD, 2002a, b). [Kl. score = 3]

In Vivo Studies

No studies were identified.

H. Carcinogenicity

No studies were identified.

I. Reproductive Toxicity

No studies were identified.

J. Developmental Toxicity

Pregnant rats were dosed by oral gavage with 0, 2.45, 11.4, 52.9 or 245 mg/kg sodium carbonate on gestational days 6 to 15. No maternal or developmental toxicity was observed. The NOAEL for maternal and developmental toxicity is 245 mg/kg-day, the highest dose tested (OECD, 2002a, b). [Kl. score = 2]

Pregnant mice were given doses of sodium carbonate (3.4 to 340 mg/kg) by oral gavage on gestational days 6 to 15. No maternal or developmental toxicity was observed. The NOAEL for maternal and developmental toxicity is 340 mg/kg-day, the highest dose tested (OECD, 2002a, b). [Kl. score = 2]

Pregnant rabbits were dosed by oral gavage with 0, 1.79, 8.31, or 179 mg/kg sodium carbonate on gestational days 6 to 15. No maternal or developmental toxicity was observed. The NOAEL for maternal and developmental toxicity is 179 mg/kg-day, the highest dose tested (OECD, 2002a, b). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

There are no repeated dose toxicity studies conducted on sodium carbonate by any route of exposure. Developmental toxicity studies conducted by the oral route in three animal species showed no developmental effects at the highest doses tested. Sodium carbonate dissociates to sodium and carbonate ions in bodily fluids, and significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms.

Sodium carbonate is used in many countries (e.g., U.S. and EU) as a food additive. It is regarded as a Generally Recognized as Safe (GRAS) substance in food with no limitation other than current good manufacturing practice (OECD, 2002a, b).

Therefore, a toxicological reference value was not derived for sodium carbonate.

The Australian drinking water guideline values for sodium (180 ppm, aesthetic) and pH may be applicable (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium carbonate does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium carbonate is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

The results of the aquatic toxicity studies conducted on sodium carbonate are presented in Table 3.

Table 3: Aquatic Toxicity Studies on Sodium Carbonate (OECD, 2002a,b)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill sunfish	96-h LC_{50}	300	2	OECD, 2002a, b
Mosquitofish	96-h LC_{50}	740	2	OECD, 2002a, b
Bluefill sunfish	24-h LC_{50}	385	4	OECD, 2002a, b
Molly	50-h LC_{50}	297	4	OECD, 2002a, b
Ceriodaphnia dubia	48-h EC_{50}	200 - 227	2	OECD, 2002a, b

There are other studies conducted on invertebrates, but the results of these studies were not included in Table 3 because of the low reliability of the data (OECD, 2002a, b). No studies on algae were identified (OECD, 2002a, b).

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

The OECD-SIDS SIAR on sodium carbonate states the following regarding the aquatic toxicity studies on sodium carbonate (OECD, 2002b):

> "In general, the available toxicity studies with sodium carbonate were not conducted according to current standard guidelines. In many cases pH, buffer capacity and/or medium composition were not discussed in the publications, although this is essential information for toxicity tests with sodium carbonate. In general, mortality of the test organisms was found at concentrations higher than 100 mg/l but for *Amphipoda*, salmon and trout lethal effects were already observed at 67-80 mg/l although these studies had a low reliability. The main factor explaining the acute aquatic toxicity of sodium carbonate is most likely the increase of the pH."

"Because the natural pH, bicarbonate and also the sodium concentration (and their fluctuations in time) varies significantly between aquatic ecosystems, it is not considered useful to derive a generic PNEC or $PNEC_{added}$."

Based on the information above, PNEC values for freshwater, sediment, and soil were not derived for sodium carbonate.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium carbonate is an organic salt that dissociates completely to sodium and carbonate ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and carbonate ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Sodium and carbonate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. Thus, sodium carbonate is not expected to bioaccumulate.

No chronic aquatic toxicity data exist on sodium carbonate; however, the acute $EC(L)_{50}$s are >1 mg/L in fish, invertebrates and algae. Therefore, sodium carbonate does not meet the screening criteria for toxicity.

The overall conclusion is that sodium carbonate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Irritant Category 2

B. Labelling

Warning

C. Pictograms



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact
Wash with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Do not induce vomiting. Rinse mouth with water. Never give anything by mouth to an unconscious person. If symptoms persist, get medical attention.

B. Firefighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Decomposition in fire may produce toxic gases.

Special Protective Equipment for Fire fighters
Full protective clothing and approved self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage and Handling

General Handling
Avoid contact with eyes and skin. Avoid creating or inhaling dust.

Storage
Store away from acids. Store in a cool, dry location.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure limit for sodium carbonate.

Engineering Controls
Use in a well ventilated area. Localised ventilation should be used to control dust levels.

Personal Protection Equipment
Respiratory Protection: In case of insufficient ventilation, wear suitable respiratory equipment. Dust/mist respirator.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium Carbonate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

De Groot *et al.* (2002). Addition of sodium carbonate to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals Int. Doc. No. 8320/48/01; cited in OECD, 2002a,b.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Eggeman T. (2001). Sodium Carbonate. In: Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons, New York, NY.

Klimisch, H. J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2002a). IUCLID Data Set for Sodium carbonate (CAS No. 497-19-8), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=7BCD380E-ADA2-4BAF-B2F7-DED360D32D7D.

OECD (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium carbonate (CAS No. 497-19-8), UNEP Publications. http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=7BCD380E-ADA2-4BAF-B2F7-DED360D32D7D.

Olivier, P.H., and Marzin, D. (1987). Study of the genotoxic potential of 48 inorganic derivatives with the SOS chromotest. Mutat. Res. 189: 263-269.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a, b.

SODIUM DIACETATE

This dossier on sodium diacetate presents the most critical studies pertinent to the risk assessment of sodium diacetate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydrogen di(acetate)

CAS RN: 126-96-5

Molecular formula: $C_4H_7NaO_4$

Molecular weight: 142.09

Synonyms: Sodium diacetate; sodium hydrogen di(acetate); sodium hydrogen diacetate; acetic acid, sodium salt (2:1); sodium acid acetate; sodium acetate, acid; sodium hydrogen acetate; sodium acetate (1:2); acetic acid, dimer, sodium salt

SMILES: CC(=O)O.CC(=O)[O-].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Diacetate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White powder	2	ECHA
Melting point	>150°C (decomposes)	2	ECHA
Density	1.405 g/cm^3 @ 20°C	1	ECHA
Vapor pressure	0 Pa @ 25°C (calculated)	2	ECHA
Partition coefficient (log K_{ow})	-3.72	2	EPA, 2019
Water solubility	1,000 g/L (very soluble)	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

B. Biodegradation

No studies are available on sodium diacetate.

Sodium acetate is readily biodegradable. In a Dissolved Organic Carbon (DOC) Die-Away test, degradation for sodium acetate was 86% after 7 days and 99% after 28 days (ECHA) [Kl score = 1].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for sodium diacetate. Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} values from log K_{ow} of -3.72 is 0.0125 L/kg (acetic acid). The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.0 L/kg (acetic acid).

D. Bioaccumulation

There are no bioaccumulation studies on sodium diacetate. Sodium diacetate is not expected to bioaccumulate based on a log K_{ow} of -3.72 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance is of low oral and dermal acute toxicity. It is not irritating to the skin but displays eye irritation. There are no sensitization data nor any repeat dose studies available. The substance is not genotoxic. Substance reproductive or developmental toxicity is not expected at typical exposure levels.

B. Acute Toxicity

The oral LD_{50} in rats is 5,600 mg/kg (ECHA) [Kl. score = 2].

No acute inhalation studies are available on sodium diacetate.

The dermal LD_{50} in rats is >2,000 mg/kg (ECHA) [Kl. score = 2].

C. Irritation

Application of 0.5 g sodium diacetate to the skin of rabbits for 4 hours under unspecified conditions was non-irritating (ECHA) [Kl. score = 2].

Instillation of 0.1 g sodium diacetate into the eyes of rabbits was severely irritating. Conjunctival redness was not fully reversible after 21 days (ECHA) [Kl. score = 1].

D. Sensitization

No studies are available.

E. Repeated Dose Toxicity

No data are available on repeat dose toxicity studies for this substance.

F. Genotoxicity

In Vitro Studies

No studies are available on sodium diacetate. Table 2 lists the in vitro genotoxicity studies on sodium acetate.

Table 2: *In vitro* Genotoxicity Studies on Sodium Acetate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	NC	-	2	ECHA
Chromosomal aberration (Chinese hamster fibroblast CHL cells)	-	NC	2	ECHA

*+, positive; -, negative; NC, not conducted.

In Vivo Studies

No studies are available on sodium diacetate or sodium acetate.

A bone marrow micronucleus study has been conducted on acetic anhydride (which hydrolyses to acetic acid). Male and female SD rats were exposed by inhalation to 0, 1, 5, or 20 ppm acetic anhydride, 6 hours/day, 5 days/week for 13 weeks. The incidence of micronucleated immature erythrocytes was not increased at any exposure concentration (ECHA) [Kl. score = 1].

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0 or various concentrations up to 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 15. There were no maternal or developmental toxicity at any dose level. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day (ECHA) [Kl. score = 2].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 16, 74.3, 345, or 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 15. There were no treatment-related effects on maternal or fetal survival, or on soft or skeletal tissues. There was no effect on the fetal development in the presence of slight maternal toxicity (reduced body weight gain) at 345 mg/kg. At 1,600 mg/kg, there was an increase in the number of litters containing a dead fetus and some reductions in ossification. The NOAELs for maternal and developmental toxicity are 74.3 and 345 mg/kg-day, respectively (ECHA) [Kl. score = 2].

Pregnant female Dutch-belted rabbits were dosed by oral gavage with 0, 16, 74.3, 345, or 1,600 mg/kg apple cider vinegar (5% acetic acid) on gestational days 6 to 18. There were no treatment-related effects on maternal or fetal survival, or on soft or skeletal tissues. There was a reduction in the pregnancy rate in the high-dose group; and a dose-dependent decrease in maternal body weights at $\geq$74.3 mg/kg. Some deaths or abortions occurred in all treated groups and some litter losses were reported at $\geq$345 mg/kg. Maternal effects were much more noticeable than the effects on fetal development. These findings have been considered a consequence of the bactericidal properties of orally administered acetic acid within the gastrointestinal tract of female rabbits, and not a direct effect on embryonic implantation and development of acetic acid (EU, 2008). It is likely that this accounts for the apparent increased sensitivity of this species to oral administration of acetic acid. The NOAEL for developmental toxicity is 1,600 mg/kg-day; a NOAEL for maternal toxicity was not identified (ECHA) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

A. Non-Cancer

Oral

There are no repeated dose toxicity studies that were considered adequate for human health risk assessment.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has maintained a group ADI of "not limited" for acetic acid and its potassium and sodium salts (JECFA).

The Australian drinking water guidance value for sodium (180 mg/L (aesthetics) and pH (6.5 to 8.5) may apply to sodium diacetate.

B. Cancer

No carcinogenicity studies are available. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium diacetate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute aquatic toxicity studies on analogs of sodium diacetate suggest a relatively low level of toxicity. Data on these studies are shown below.

B. Aquatic Toxicity

Acute Studies

There are no studies on sodium diacetate. Table 3 lists the results of acute aquatic toxicity studies read-across from sodium acetate and potassium acetate. Read-across is justified since all three substances dissociate to the acetate anion and their respective cations (Na^+ or K^+). The toxicity of these substances is expected to be driven by the acetate ion, with the cations having a minor role.

Table 3: Acute Aquatic Toxicity Studies on Sodium Acetate and Potassium Acetate

Test Species	Test Substance	Endpoint	Results (mg/L)	Klimisch score	Reference
Brachydanio rerio	Sodium acetate	96-hr LC_{50}	>100 173*	1	ECHA
Daphnia magna	Sodium acetate	48-hr EC_{50}	>1,000 1,730*	2	ECHA
Daphnia magna	Potassium acetate	48-hr EC_{50}	>459.5 665*	2	ECHA
Skeletonema costatum	Potassium acetate	72-hr EC_{50}	>500 724*	2	ECHA

*Values converted to sodium diacetate using the molecular weights of sodium acetate (82.03 g/mol), potassium acetate (98.15 g/mol), and sodium diacetate (142.09 g/mol).

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for sodium diacetate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (173 mg/L), invertebrates (665 mg/L), and algae (724 mg/L). On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported $E(L)C_{50}$ value of 173 mg/L for fish. The $PNEC_{water}$ is 1.7 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. The $PNEC_{soil}$ value was calculated using the equilibrium partition method. The $PNEC_{soil}$ is 0.02 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.02/1500) \times 1000 \times 1.7$
$= 0.02$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1.0 \times 0.02$
$= 0.02$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for sodium diacetate calculated from EPISUITE™ using the molecular connectivity index (MCI) is 1.0 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium diacetate is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -3.72, sodium diacetate does not meet the screening criteria for bioaccumulation.

There are no aquatic chronic toxicity data for sodium diacetate (or its surrogates). The acute $E(L)C_{50}$ values for sodium acetate and potassium acetate (read-across to sodium diacetate) are >1 mg/L. Thus, sodium diacetate does not meet the screening criteria for toxicity.

The overall conclusion is that sodium diacetate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye damage Category 1

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air.

Ingestion
Rinse mouth with water and then drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention..

B. Fire Fighting Information

Extinguishing Media
Water spray or fog, carbon dioxide, dry powder.

Specific Exposure Hazards
Burning may produce harmful and toxic fumes.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus if exposed to vapors, fumes or combustion products

C. Accidental Release Measures

Personal Precautions
No special precautions are necessary. Ensure adequate ventilation.

Environmental Precautions
Do not discharge into drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilt
For large amounts: dike spillage and pump off the product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling
Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions
Protect against fire and explosion: prevent electrostatic charge; sources of ignition should be kept well clear, and fire extinguishers should be kept handy.

Storage
Keep container tightly closed and dry. Protect against heat. The most favorable course of action is to use an alternative chemical product with less inherent propensity for occupational exposure or environmental contamination. Recycle any unused portion of the material for its approved use or return it to the manufacturer or supplier. Ultimate disposal of the chemical must consider: the material's impact on air quality; potential migration in soil or water; effects on animal, aquatic, and plant life; and conformance with environmental and public health regulations.

E. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for sodium diacetate.

Engineering Controls
Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment
Respiratory Protection: Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Body protection must be chosen depending on activity and possible exposure.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium diacetate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

JECFA: http://apps.who.int/ipsc/database/evaluations/chemical.aspx?chemID=4785.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

SODIUM HYDROXIDE

This dossier on sodium hydroxide presents the most critical studies pertinent to the risk assessment of sodium hydroxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the OECD-SIDS documents on sodium hydroxide (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydroxide

CAS RN: 1310-73-2

Molecular formula: HNaO

Molecular weight: 40 g/mol

Synonyms: Caustic soda, soda lye, NaOH

SMILES: O[Na]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Sodium Hydroxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	Lide, 2009; ECHA
Melting Point	318°C (solid, 100%); 52°C (60% solution)	2	ECHA
Boiling Point	1,388°C @ 101.3 kPa	2	Lide, 2009; ECHA
Density	2130 kg/m^3, 20°C (100%) 1430 kg/m^3, 20°C (40%)	2	Lide, 2009; ECHA
Vapour Pressure	1 Pa @ 513°C	2	Lide, 2009; ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble (>10 g/L @ 25°C)	2	Lide, 2009; ECHA
Dissociation Constant (pKa)	14.8 @ 25°C	2	Lide, 2009; ECHA
pH of 5% NaOH solution	14	2	O'Neil, 2006

Sodium hydroxide (NaOH) is a strong alkaline substance that dissociates completely in water to sodium (Na^+) and hydroxyl (OH^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility and low vapour pressure, sodium hydroxide will be found predominantly in the aquatic environment where it dissociates completely to sodium (Na^+) and hydroxyl (OH^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of sodium hydroxide to an aquatic ecosystem may increase the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of sodium hydroxide into the aquatic environment from the use of NaOH could potentially increase the sodium concentration and the pH in the aquatic environment. Table 2 shows the concentration of sodium hydroxide needed to increase the pH to values of 9.0, 10.0, 11.0 and 12.0.

Table 2: Sodium Hydroxide Concentration (mg/L) Needed to Increase pH (DeGroot et al., 2002; taken from OECD, 2002b)

Buffer capacity*	Final pH			
	9.0	10.0	11.0	12.0
0 mg/L HCO_3 (distilled water)	0.4	4.0	40	400
20 mg/L HCO_3 (10th percentile of 77 rivers)	1.0	8.2	51	413
106 mg/L HCO_3^- (mean value of 77 rivers)	3.5	26	97	468
195 mg/L HCO_3^- (90th percentile of 77 rivers)	6.1	45	145	525

*The initial pH of a bicarbonate solution with a concentration of 20-195 mg/L was 8.25 to 8.35.

Na^+ and OH^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Limited toxicity data exist for sodium hydroxide (NaOH). Depending on the concentration, solutions of NaOH are corrosive, irritating or non-irritating. These solutions cause direct effects to the skin, eyes, respiratory tract and gastrointestinal tract. Vapours from aqueous solutions of KOH can cause respiratory irritation. NaOH is not a skin sensitiser. There are no repeated dose, reproductive and developmental toxicity studies on sodium hydroxide.

B. Toxicokinetics/Metabolism

Sodium hydroxide dissociates completely in aqueous solutions to sodium (Na^+) and hydroxyl (OH^-) ions. Sodium is an essential nutrient involved in fluid and electrolyte balance and is required for normal cellular function (Ganong, 1995). Sodium is the major extracellular cation in the body; the total body content is tightly regulated (Ganong, 1995).

C. Acute Toxicity

There are no oral toxicity guideline studies on sodium hydroxide. An oral LD_{50} of a 1 to 10% solution of NaOH in rabbits was reported to be 325 mg/kg (expressed as 100% NaOH) (OECD, 2002a,b). Mortality was also observed when a 1% NaOH solution was dosed, but in this case, the applied volume was relatively high (24 mL per kg body weight) (OECD, 2002a,b).

Acute toxicity studies were not identified for the inhalation and dermal route.

D. Irritation

Animal studies have shown that an 8% NaOH solution is corrosive to the skin. In humans, 0.5 to 4% NaOH concentrations produced skin irritation; and, based on the results of two different human patch tests, a NaOH solution that is slightly less than 0.5% would be non-irritating to human skin (OECD, 2002a,b).

Results from animal eye irritation studies indicate that a 0.2-1.0% NaOH solution would be non-irritating, while 1.2 or > 2% NaOH solutions would be corrosive (OECD, 2002a,b).

E. Sensitisation

Male volunteers were exposed on the skin of their back to solutions of 0.063 to 1.0% NaOH in the induction phase of a human patch test. After 7 days the volunteers were challenged to a concentration of 0.125% NaOH. The irritant response correlated well with the concentration of NaOH, but an increased response was not observed when the previously patch tested sites were re-challenged. Based on this study, sodium hydroxide is not a skin sensitiser (OECD, 2002a,b; ECHA) [Kl. score = 2].

F. Repeated Dose Toxicity

No studies were identified for the oral and dermal route. An inhalation study was conducted in rats exposed to aerosols of solutions of NaOH ranging from 5% to 40%. Exposures were twice weekly (hours/day and total exposure days unspecified). All animals in the 40% solution group died within a month mostly from bronchopneumonia. At the lower concentrations, respiratory tract lesions were observed; an NOAEL was not identified (NIOSH, 1975).

G. Genotoxicity

In Vitro Studies

Several *in vitro* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

In Vivo Studies

Several *in vivo* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

H. Carcinogenicity

No studies were identified.

I. Reproductive Toxicity

No valid studies were identified regarding toxicity to reproduction in animals after oral, dermal or inhalation exposure to NaOH.

J. Developmental Toxicity

No valid studies were identified regarding developmental toxicity in animals after oral, dermal or inhalation exposure to NaOH (OECD, 2002a,b; ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Oral and dermal repeated dose, reproductive, and developmental toxicity studies have not been conducted on NaOH. A repeated dose toxicity study was conducted by the inhalation route, but the methodology and documentation preclude its use for deriving a toxicological reference value. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of NaOH, which would limit the amount absorbed. NaOH dissociates to sodium and hydroxyl ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, a toxicological reference value was not derived for NaOH.

The Australian drinking water guideline values for sodium (180 ppm, aesthetic) and pH may be applicable (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium hydroxide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium hydroxide has low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

The OECD-SIDS SIAR on NaOH states that while the toxicity of the NaOH has been assumed to be related to the hydroxyl anion, in general a pH change could influence the speciation of other chemicals and therefore increase and/or decrease toxicity of the substance.

There are no guideline studies on NaOH; the studies summarised below have Klimisch scores of 3 or 4.

Acute Fish

The 24-hour LC_{50} to *Carassius auratus* (goldfish) is 160 mg/L. At 100 mg/L, which was equivalent to a pH of 9.8, no mortality was observed. The 48-hour LC_{50} to *Leuciscus idus melanotus* is 189 mg/L. The 96-hour LC_{50} of *Gambusia affinis* (mosquitofish) is 125 mg/L. At 84 mg/L, no effects on the fish were observed. The pH was 9 at 100 mg/L.

Acute Invertebrate

The 48-hour LC_{50} is 40 mg/L for *Ceriodaphnia cf. dubia*. The toxicity threshold concentration of NaOH for *Daphnia magna* was reported to range from 40 to 240 mg/L.

Acute Algae

No studies were identified.

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

The OECD-SIDS SIAR on NaOH states the following regarding the aquatic toxicity studies on NaOH (OECD, 2002b):

> *"In many cases pH, buffer capacity and/or medium composition were not discussed in the publications, although this is essential information for toxicity tests with NaOH. This is the most important reason why most of the studies, mentioned above were considered invalid. Although valid acute ecotoxicity tests and chronic ecotoxicity tests with NaOH are not available, there is no need for additional testing with NaOH. A significant number of acute toxicity tests are available, and the results of the tests are more or less consistent. Altogether they give a sufficient indication of acute toxicity levels of sodium hydroxide."*
>
> *"Furthermore, acute toxicity data cannot be used to derive a PNEC or a PNEC added for sodium hydroxide. Aquatic ecosystems are characterised by an alkalinity/pH, and the organisms of the ecosystem are adapted to these specific natural conditions. Based on the natural alkalinity of waters, organisms will have different optimum pH conditions, ranging from poorly buffered waters with a pH of 6 or less to very hard waters with pH values up to 9. A lot of information is available about the relationship between pH and ecosystem structure and also natural variations in pH of aquatic ecosystems have been quantified and reported extensively in ecological publications and handbooks."*
>
> *"Normally a PNEC or a PNEC added has to be derived from the available ecotoxicity data. A PNEC added is a PNEC which is based on added concentrations of a chemical (added risk approach). Based on the available data it is not considered useful to derive a PNEC or a PNEC added for NaOH because:*
>
> - *The natural pH of aquatic ecosystems can vary significantly between aquatic ecosystems,*

- *Also, the sensitivity of the aquatic ecosystems to a change of the pH can vary significantly between aquatic ecosystems and*
- *The change in pH due to an anthropogenic NaOH addition is influenced significantly by the buffer capacity of the receiving water."*

"Although a PNEC or a PNEC added was not calculated for NaOH, there is a need to assess the environmental effect of a NaOH (alkaline) discharge. Based on the pH and buffer capacity of effluent and receiving water and the dilution factor of the effluent, the pH of the receiving water after the discharge can be calculated. Of course, the pH change can also be measured very easily via a laboratory experiment or by conducting field measurements. The change in pH should be compared with the natural variation in pH of the receiving water and based on this comparison it should be assessed if the pH change is acceptable."

Based on the information above, PNEC values for freshwater, sediment, and soil were not derived for sodium hydroxide.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium hydroxide is an inorganic salt that dissociates completely to sodium and hydroxide ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and hydroxide ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Sodium and hydroxide ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, sodium hydroxide is not expected to bioaccumulate and does not meet the screening criteria for bioaccumulation.

No chronic toxicity data exist on sodium hydroxide; however, the acute EC_{50} values are > 1 mg/L in fish, invertebrates and algae. Thus, sodium hydroxide does not meet the screening criteria for toxicity.

The overall conclusion is that sodium hydroxide is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Metal Corrosive Category 1

Skin Corrosive, Category 1A

Eye Damage, Category 1

EU Concentration Limits:
≥ 5%: Skin Corrosive 1A
≥ 2 to <5%: Skin Corrosive 1B

≥ 0.5%to <2%: Skin Irritant Category 2
≥ 0.5% to <2%: Eye Irritant Category 2

In addition to the hazard statements corresponding the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

C. Pictograms



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Flush with plenty of fresh water for 15 minutes holding eyelids open, lifting eyelids occasionally to ensure complete removal of the product. Remove contacts, if present and easy to do. DO NOT allow rubbing of eyes or keeping eyes closed. Seek medical attention.

Skin Contact

Rinse with soap and plenty of water for several minutes. Remove contaminated clothing. Seek medical attention immediately.

Inhalation

Remove person to fresh air. Apply artificial respiration if not breathing. Seek medical attention.

Ingestion

Rinse mouth with water (only if the person is conscious), but do not administer fluids. Do NOT induce vomiting. Seek medical attention immediately.

B. Fire Fighting Information

Extinguishing Media

Carbon dioxide, water spray, foam, dry chemical.

Specific Exposure Hazards

Containers may explode when heated. May form explosive mixtures with strong acids. Hazardous combustion products may include the following materials: halogenated compounds, metal oxides/oxides, sodium monoxide.

Special Protective Equipment for Firefighters

Full protective clothing and approved self-contained breathing apparatus required for firefighting personnel.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment and avoid direct contact. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Ventilate the area before entry.

Environmental Precautions

Prevent spills from entering storm drains or sewers and contact with soil.

Steps to be Taken if Material is Released or Spilt

Use an absorbent material to recover as much product as possible, then rinse the affected area with water to dilute the residue. Disposal of leftover product and used containers should be carried out in accordance with all local, state and federal regulations.

D. Storage and Handling

General Handling

Wear appropriate personal protective equipment. Avoid contact with eyes, skin or clothing. Avoid breathing mist, vapours or spray. Use only with adequate ventilation. Wash hands after use. Launder contaminated clothing.

Storage

Store away from acids. Keep container closed when not in use. Store in a cool well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for sodium hydroxide in Australia is 2 mg/m^3 as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: Use a mask or approved air-purifying respirator with appropriate cartridge or canister in spray applications or in confined spaces.

Hand Protection: Wear impervious gloves to prevent skin contact and absorption of this material. Rubber or Neoprene gloves may afford adequate skin protection.

Skin Protection: Wear appropriate clothes (i.e., coveralls). Use non-slip footwear.

Eye Protection: Wear eye protection in situations where splash or thick mists are possible.

Other Precautions: Avoid contact with skin, eyes and clothing. When using, do not eat or drink. Wash hands thoroughly with soap and water before eating or drinking. Remove contaminated clothing and launder before reuse.

F. Transport Information

For sodium hydroxide solutions of > 5%:
Australian Dangerous Goods
UN1824, Corrosive liquid, (Sodium hydroxide solution)
Class 8
Packing Group: II

Lower concentrations of sodium hydroxide may require a different packing group or may not require any hazard code if the concentration of NaOH is low enough not to be considered a corrosive material.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

De Groot et al. (2002). The addition of sodium hydroxide to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals Int. Doc. No. 8320/47/01; cited in OECD, 2002a,b.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

NIOSH. (1975). National Institute of Occupational Safety and Health: Criteria Document: Sodium Hydroxide p.46 (1975) DHEW Pub. NIOSH 76-105; cited in NICNAS IMAP assessment report for sodium hydroxide, https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1406#cas-A_1310-73-2.

O'Neil, M.J. [Ed.]. (2006). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. P. 1485, Whitehouse Station, NJ: Merck and Co., Inc.

OECD. (2002a). IUCLID Data Set for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

SODIUM IODIDE

This dossier on sodium iodide presents the most critical studies pertinent to the risk assessment of sodium iodide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium iodide

CAS RN: 7681-82-5

Molecular formula: NaI

Molecular weight: 149.89 g/mol

Synonyms: Ioduril, Sodium iodide (NaI), sodiumiodide, Sodium monoiodide, Soiodin, Iodure de sodium, Natriumjodid, Natriumiodid

SMILES: [Na+].[I-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Iodide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White odorless crystalline solid	1	ECHA
Melting point	659°C	1	ECHA
Boiling point	1,304°C	1	ECHA
Density	3.5 g/cm^3 @ 25°C	1	ECHA
Vapor pressure	133.32 Pa @ 767°C	1	ECHA
Partition coefficient (log K_{ow})	No applicable (inorganic salt)	-	-
Water solubility	165 g/L @ 25°C	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Sodium iodide dissociates in water to (Na^+) and (I^-) ions. Biodegradation is not applicable to inorganic salts. As inorganic ions, Na^+ and I^- are unlikely to adsorb on the particulate matter.

Neither the Na^+ nor I^- ions are bioaccumulative. Sodium (Na^+) ions are essential to all living organisms, and its intracellular and extracellular concentrations are actively regulated (Ganong, 1995). Iodine is essential for thyroid hormone synthesis in vertebrate species. Ingested iodine is converted to iodide (I^-) and absorbed. The minimum daily iodine intake that will maintain normal thyroid function is 150 μg in adult humans (Ganong, 1995).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium iodide is not considered acutely toxic by any route of exposure, but any potential toxicity would be limited to the oral route as the size of iodide crystals precludes inhalation or dermal exposure. Likewise, it is not considered irritating to skin or eyes and has a history of therapeutic use that has not found evidence of sensitivity except in certain hypersensitive individuals. Iodide is not a sensitizing agent. Although evidence exists for toxicity via repeated doses that can disrupt thyroid hormones, iodine is an essential nutrient and lack of intake is associated with sub-clinical hypothyroidism. Iodide is not genotoxic, mutagenic or carcinogenic. Iodide is not toxic to reproductive endpoints or embryonically toxic, but developmental toxicity was showed under concentration of 0.1% in diet. However, this value is much higher than the temporary most tolerated dose of 1.0 mg iodine/day, set by the FAO/WHO Joint Expert Meeting on Food Additives.

The following sections detail the available and relevant literature on the toxicity of iodide. The information described below was obtained from NICNAS IMAP if available and the ECHA database. Please refer to those information sources for the studies referenced therein.

B. Acute Toxicity

Sodium iodide is not considered acutely toxic by any route of exposure. The potential acute toxicity of sodium iodide is limited to the ingestion pathway as the crystal size precludes both dermal and inhalation exposure. The most relevant study on vertebrates by oral route is a company study (A. Hausner, G. Weise, and A. Hofmann, 1980) (Kl = 2). In the test the effects of iodide were studied in male and female Wistar rats. 10 male

and 10 female in each dose and control groups were administrated with potassium iodide for 14 days at dose of 0 (control), 2000, 2500, 2800 3200, 3600, and 4000 mg/kg body weight mg/kg bw respectively. This study calculated a 24 hour and 7-14 days of LD50 to rats (male/female) of 3118 and 2779 mg/kg bw, respectively under test conditions.

C. Irritation

Based on existing information, iodide does not meet the skin or eyes irritation/corrosion criteria under the Regulation (EC) No. 1272/2008 nor Directive 67/548/EEC. Iodide has no effect to the human skin. Iodine has been used for dermal application in human as disinfectant (as Iodine and Povidine Iodine) for long time. The mechanism of disinfecting is oxidizing bactericide by iodine; meanwhile the iodine is reduced to iodide. It can be assumed that following application of iodine on skin, there is iodide exposure to the epidermis. Further, in a human assay, potassium iodide in concentrations ranging from 5% to 20% in petrolatum was applied to skin with negative reactions.

There are no recent acceptable studies evaluating iodide effects on eye irritation, but iodide has been evaluated and the results are negative for irritation. Although there is some exceptional case showing the iodide can have different degrees of impact on eyes, most reports gave negative results. Testing of potassium iodide on rabbit eyes by injection of 3% solution into the cornea has caused only slight reaction. In a report of large-scale intravenous injections given to patients with eye diseases, some individuals hypersensitive to iodide displayed watery rhinitis, lacrimation, edema of the eyelids, and conjunctival hyperemia. Rarely, superimposed infection may cause more serious disturbances, and in one instance hypopyon was observed in the anterior chambers. Serious involvement of the eyes in iodism is uncommon, but in two patients severe keratoconjunctivitis was reported and in one of these there were hemorrhagic iritis and vitreous opacities. The eyes recovered when iodides were discontinued. The ordinary signs and symptoms of iodism clear up promptly when iodides are stopped.

D. Sensitization

Based on the properties of sodium iodide, it does not meet classification criteria of skin and respiration sensitisation under Regulation (EC) No. 1272/2008 or Directive 67/548/EEC. The lack of sensitization to sodium iodide is thought to be driven by the large crystal size preventing inhalation and epidermal penetration.

E. Repeated Dose Toxicity

The most likely route for human exposure is via ingestion, so the dermal and inhalation route are irrelevant in the repeated toxicity assessment.

Boyages et al. (1989) compared thyroid status in groups of children 7–15 years of age who resided in two areas of China where drinking-water iodide concentrations were either 462.5 µg/l (n = 120) or 54 µg/l (n =51). Urinary iodine concentrations were 1236 µg/g creatinine in the high-iodine group and 428 µg/g creatinine in the low-iodine group. Although the subjects were all euthyroid, with normal values for serum thyroid hormones and TSH concentrations, TSH concentrations were significantly higher ($P < 0.05$) in the high-iodine group. The high-iodine group had a 65% prevalence of goiter and a 15% prevalence of Grade 2 goiter compared with 15% for goiter and 0% for Grade 2 goiter in the low-iodine group. To transform the measured urinary iodine levels into estimates of iodine intakes, steady state baseline dietary intakes of iodide were assumed to be equivalent to the reported 24-h urinary iodine excretion rates. Assuming a body weight of 40 kg and lean body mass of 85% of body weight, the urinary iodine/creatinine ratios reported by Boyages et al. (1989) can be converted to approximate equivalent intake rates of 1150 µg/day (0.029 mg/kg body weight per day) and 400 µg/day (0.01 mg/kg body weight per day) for the high- and low-iodine groups, respectively. Thus, the NOAEL for this study is considered to be 0.01 mg/kg body weight per day.

Supporting studies indicate that the NOAEL from the Boyages et al. (1989) study would be applicable for both acute and chronic-duration exposure of elderly adults, who may represent another sensitive subpopulation (Chow et al., 1991; Szabolcs et al., 1997). In the Chow et al. (1991) study, 30 healthy 60 to 75-year-old females received daily doses of 500 µg iodine per day for 14 or 28 days. Serum concentrations of free T4 were significantly decreased, and serum TSH concentrations were significantly elevated. On average, the magnitude of the changes did not produce clinically significant depression in thyroid hormone levels; however, five subjects had serum TSH concentrations that exceeded 5 mU/l. The pre-existing dietary iodine intake was approximately 72-100 µg/day, based on urinary iodide measurements. Therefore, the total iodide intake was approximately 600 µg/day (0.0087 mg/kg body weight per day, based on a mean weight of 69 kg for women 19–64 years of age in the British National Diet and Nutrition Survey; British Nutrition Foundation, 2004). Szabolcs et al.(1997) studied elderly nursing home residents who had received long-term exposure to iodine in one of three regions where the intakes were estimated to be approximately 117, 163, or 834 µg/day (0.0017, 0.0023, or 0.012 mg/kg body weight per day for low, moderate, or high intake, respectively). The prevalence of clinical hypothyroidism was 0.8%, 1.5%, and 7.6% in the low-, moderate-, and high-iodine groups, respectively. Serum TSH concentrations were elevated as free T4 levels were reduced ($P = 0.006$).

In a study by Paul et al. (1988), healthy euthyroid adults (nine males, nine females) who had no history of thyroid disease or detectable antithyroid antibodies received daily oral doses of 250, 500, or 1500 µg iodine (as sodium iodide) per day for 14 days. Based on 24-h urinary excretion of iodide prior to the iodide supplement, the background iodine intake was estimated to be approximately 200 µg/day; thus, the total iodide intake was approximately 450, 700, or 1700 µg/day (approximately 0.0064, 0.01, or 0.024 mg/kg

body weight per day, assuming a 70-kg body weight). Subjects who received 1700 µg/day (0.024 mg/kg body weight per day) had significantly depressed (5–10%) serum concentrations of total T4, free T4, and total T3 compared with pretreatment levels, and serum TSH concentrations were significantly elevated (47%) compared with pretreatment values. Hormone levels were within the normal range during treatment. In this same study, nine females received daily doses of 250 or 500 µg iodine per day for 14 days (total intake was approximately 450 or 700 µg/day; 0.0064 or 0.010 mg/kg body weight per day), and there were no significant changes in serum hormone concentrations.

In a comparable quality study by Gardner et al. (1988), 10 healthy adult euthyroid males received daily oral doses of 500, 1500, or 4500 µg iodine (as sodium iodide) per day for 14 days. Based on 24-h urinary excretion of iodide of 256–319 µg/day prior to the iodide supplement, the total estimated intakes were 800, 1800, or 4800 µg/day, or approximately 0.011, 0.026, or 0.069 mg/kg body weight per day. In this study, there were no effects on serum thyroid hormone or thyroid stimulating hormone (TSH) concentrations at the 800 µg/day intake (0.011 mg/kg body weight per day); however, intakes of 1800 or 4800 µg iodine per day (0.026 or 0.069 mg/kg body weight per day) produced small (10%), but significant, transient decreases in serum thyroid hormone concentrations and an increase (48%) in serum TSH concentration, relative to the pretreatment values.

From the Boyages et al. (1989) study, supported by the studies of Gardner et al. (1988), Paul et al. (1988), and others, a TDI of 0.01 mg/kg body weight, based upon reversible subclinical hypothyroidism, can be established by dividing the NOAEL of 0.01 mg/kg body weight per day by an uncertainty factor of 1.

However, iodine is also an essential trace element for synthesis of thyroid hormones. In healthy adults, sub-clinical hypothyroidism is associated with intakes of 1.7 to 1.8 mg/day, and for children with intakes of 1.15 mg/day (EFSA 2006, FSANZ 2008). Chronic iodine intakes of approximately 1 mg/day, however, appear to be well tolerated by healthy adults. This is consistent with the provisional maximum tolerated daily intake of 1 mg/day established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA 1989), and the nutrient reference value and tolerable upper intake level of 1.1 mg/day respectively recommended by the NHMRC (2006) and Food Standards Australia New Zealand (FSANZ 2008) for iodine intake by adults in Australia and New Zealand. This value has been used as the basis for calculating the drinking water guideline described in Section V.

F. Genotoxicity

The mutagenic potential for iodide (in potassium iodide) was studied using the L5178Y mouse (TK+/-) lymphoma assay (Kessler et al., 1980). The established mutagens ethylmethanesulphonate (EMS) and dimethylnitrosamine (DMN) were highly active in

this assay, whereas iodide was inactive. Using the BALB/c 3T3 transformation assay well assessed the transformational capacities of these same agents and the positive mutagen N-ethyl-N-nitro-N-nitrosoguanidine. All concentrations of the iodide tested were inactive in this assay.

Another study (J.M. Poul,, and P. Sanders, 2004) on genotoxic effects of potassium iodide was conducted in vitro using the alkaline comet assay at concentration of 0.625, 1.25, 2.5, 5 and 10 mM. Additionally, in the test cell viability was also measured using the Trypan blue exclusion method and expressed as proportion of total cells. The test results showed that potassium iodide did not induced DNA damage or cytotoxicity in the alkaline comet assay for doses up to 10 mM.

In the same study, the chromosome damage effects of potassium iodide were evaluated in vitro using cytokinesis-block micronucleus test at concentration of 0.625, 1.25, 2.5, 5 and 10 mM. Additionally, in the test cytotoxicity was also measured by the binucleated (BN) cell ratio between treated and control slides. The test results showed that potassium iodide did not induce chromosome damage or cytotoxicity in the alkaline comet assay for doses up to 10 mM.

In an in vivo chromosome aberration test on embryonic hepatocytes, Stable iodine of 10 mg/kg is administered to the rats 7 days after fertilization. Then the embryonic liver was homogenized and the cells in metaphase were stained and checked under metaphase. The chromosome aberration cells were counted respectively for the concentration group and control group. The chromosome aberration rate in the concentration group was compared with that in the control group. The result showed there was no significant difference between iodide dosed group with the control group.

Based on the available studies summarized above, iodide has neither genetic toxicity nor cytotoxicity to mammalian cells.

G. Reproductive and Developmental Toxicity

Iodide is not considered to meet the reproductive/developmental criteria under the Regulation (EC) No. 1272/2008 nor Directive 67/548/EEC. Several studies have evaluated reproductive and developmental effects.

A study (Kl = 2) was conducted with rats to determine the effects of intake of the test chemical. Females were bred to normal males, wherein the test chemical was added to the diet during the latter portion of gestation and the females were permitted to litter normally. The effect of the treatment on gestation period, lactation and survival of the young was observed Gestation time for rats was not affected but prolonged parturition was observed. In fetal parameters, average mortality was slightly greater for young fed with the test chemical while the weaning weight was significantly less than that of

controls. Female rats re-bred after removal of dietary intake of the test chemical gave birth and nursed litters normally. The study resulted in a LOAEL of 150 mg/kg bw.

The effect of the test chemical on the reproductive performance of female minks was investigated (Kl = 2). Female mink were administered with 0, 10, 100, or 1000 ppm of the test chemical, in diet for 18 days, from breeding through lactation. Gestation periods of the test chemical-treated mink were shorter than the controls. Kit birth weights were not significantly different from the controls. The average number of kits whelped per female mated in the control group was 5.0. Only 2.1 kits per female mated were whelped by the mink fed 100 ppm supplemental test chemical and none of the females that received the 1000 ppm supplemental test chemical diet whelped. Body weights of kits whelped and nursed by the females that received the 100 ppm supplemental test chemical diet were significantly lighter at 4 weeks of age. No detrimental effects were observed on litter size or kit survival in the group fed 10 ppm supplemental test chemical, and hence the NOAEL for reproductive toxicity in female minks is determined to be 10 ppm of the test chemical in the diet.

Iodide was administered in diet to male and female Sprague-Dawley rats before and during breeding, to females only during gestation and lactation, at levels of 0, about 23, 45 and 90 mg/kg bw [0, 0.025, 0.05 or 0.1% (w/w)]. Dams in a positive control group were given 4 mg/kg i.p. of the anti-mitotic/cytotoxic drug 5-azacytidine on day 17 of gestation. The LOAEL value for the test chemical in rats is found to be about 90 mg/kg/day (0.1%). At this dose level, the test chemical did not produce any significant reduction in parental body weight or food consumption, though it significantly reduced litter size and increased offspring mortality. The LOAEL value for the test chemical is found to be about 45 mg/kg/day (0.05%) for the F1 generation based on the effect of decreased pre-weaning body weights in the offspring, delay in auditory startle and delayed olfactory orientation from the home-cage scent. Overall, the data in this experiment (Kl =2) support the view that the test chemical at doses of up to 0.1% in the diet of growing rats produces evidence of developmental toxicity.

In a one-generation (experiment I) and fertility (experiment II) reproductive study (Kl =2), pregnant female Wistar rats were given fluid orally on a regular basis at dose levels of 0.1% (w/v) or 1% (w/v) of the test chemical. Treatment with 1% (w/v) solution led to reduced body weight and fluid intake, enlarged adrenal glands and the level of implantation was reduced. No change in food or fluid intake was seen for rats treated with 0.1% (w/v) solution. In addition, the 0.1% (w/v) of the test chemical solution-treated rats showed a high rate of implantation. Since 0.1% (w/v) of the test chemical is regarded as a high value intake and it is concluded that the test chemical has no effect on reproductive toxicity when orally administered. Neither has it provided any further information about the possible functional significance of the test chemical endometrial concentration in female rats during early pregnancy.

In conclusion, iodide is not toxic to reproductive endpoints or embryonically toxic, but developmental toxicity was showed under concentration of 0.1% in diet. However, this value is much higher than the temporary most tolerated dose of 1.0 mg iodine/day, set by the FAO/WHO Joint Expert Meeting on Food Additives.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

An oral RfD for sodium iodide was not derived because there is an existing Australian drinking water guidance value of 0.5 mg/L for iodide (health) and 180 mg/L for sodium (aesthetics). The substance is not carcinogenic, so a cancer reference value was not developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium iodide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

B. Aquatic Toxicity

The acute aquatic toxicity studies conducted on the substance suggest a wide range of toxicity that is species dependent. The results of the studies are shown below.

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on sodium iodide.

Table 2: Acute Aquatic Toxicity Studies on Sodium Iodide

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-hr LC_{50}	>100	2	ECHA
Daphnia magna	48-hr EC_{50}	0.17	2	ECHA

Chronic Studies

The 21-day NOEC in a *Daphnia* reproduction test is 91 mg/L (ECHA) [Kl. score = 2]. In another *Daphnia* reproduction test, the 21-day NOEC was 14 mg/L (ECHA) [Kl. score = 2].

The 8-day LOEC to green algae *Scenedesmus quadricauda* was 2,370 mg/L (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for sodium iodide follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute E(L)C_{50} values are available for fish (>100 mg/L) and invertebrates (0.17 mg/L). Results from chronic studies are available for invertebrates (14 mg/L) and algae (2,370 mg/L). On the basis that the data consists of short-term studies for two trophic levels and long-term results studies for two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOEC or E(L)C_{50} value of 0.17 mg/L for *Daphnia*. The $PNEC_{water}$ is 0.0034 mg/L.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of sodium iodide is dominated by its water solubility. Sorption of sodium iodide should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium iodide. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on the its properties, sodium iodide is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium iodide is an organic salt that dissociates completely to sodium and iodide ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions. For the purposes of this PBT assessment, the persistent criteria is not considered applicable to sodium iodide or its dissociated ions.

Sodium ions are essential all living organisms and its intracellular and extracellular concentrations are actively regulated. The iodide ion is essential for thyroid function which is found in all vertebrates. Thus, sodium iodide is not expected to bioaccumulate.

The lowest NOEC value on sodium iodide is >0.1 mg/L for invertebrates and algae. However, the lowest acute E(L)C_{50} value is <1 mg/L for invertebrates. Thus, sodium iodide meets the criteria for toxicity.

Therefore, sodium iodide is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute toxicity, Oral (Category 5)
Skin irritation (Category 2)
Eye irritation (Category 2A)
Acute aquatic toxicity (Category 1)

B. Labelling

Warning

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush eyes with plenty of water for at least 15 minutes, lifting lower and upper eyelids occasionally. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention immediately.

Skin Contact
Wipe off excess material from skin then immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Inhalation
Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give Oxygen. Get medical attention.

Ingestion
Induce vomiting immediately as directed by medical personnel. Never give anything by mouth to an unconscious person. Get medical attention.

Notes to Physician
No data available.

Medical Conditions Aggravated by Exposure
No data available.

Emergency Personnel Protection
No data available.

B. Fire Fighting Information

Extinguishing Media
Sodium iodide is not considered a fire hazard. Use any means suitable for extinguishing surrounding fire.

Specific Exposure Hazards
Non-combustible, substance itself does not burn but may decompose upon heating to produce corrosive and/or toxic fumes.

Special Protective Equipment for Firefighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

C. Accidental Release Measures

Personal Precautions
Use personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. Isolate hazard area. Keep unnecessary and unprotected personnel from entering.

Environmental Precautions
Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.

Substance may decompose upon heating to produce corrosive and/or toxic fumes. Do not allow run-off from fire-fighting to enter drains or water courses.

Steps to be Taken if Material is Released or Spilled
Pick up and place in a suitable container for reclamation or disposal, using a method that does not generate dust.

D. Storage and Handling

General Handling
Wear personal protective equipment. Ensure adequate ventilation. Avoid dust formation. Avoid contact with skin, eyes and clothing. Do not breathe dust. Do not ingest. Containers of this material may be hazardous when empty since they retain product residues (dust, solids.) Observe all warnings and precautions listed for the product.

Other Handling Precautions
Protect from light.

Storage
Keep in a tightly closed container, stored in a cool, dry, ventilated area. Protect against physical damage. Isolate from incompatible substances.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
None established.

Engineering Controls
Ensure adequate ventilation, especially in confined areas. Ensure that eyewash stations and safety showers are close to the workstation location.

Personal Protection Equipment
Respiratory Protection:
When workers are facing exposure to dust or mist, they must use appropriate certified respirators. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly.

Hand Protection:
Wear protective gloves; inspect gloves before use.

Skin Protection:
Wear clean body-covering clothing.

Eye protection:
Use chemical safety goggles. Maintain eye wash fountain and quick-drench facilities in work area.

Other Precautions:
None noted.

F. Transport Information

UN Number UN3077
Hazard class 9

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

AICS: Listed

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

SODIUM PERBORATE TETRAHYDRATE

This dossier on sodium perborate tetrahydrate presents the most critical studies pertinent to the risk assessment of sodium perborate tetrahydrate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): sodium perborate tetrahydrate

CAS RN: 10486-00-7

Molecular formula: $NaBO_3 \bullet 4H_2O$

$[NaBO_2(OH)_2 \bullet 3H_2O]_2$ (presented as the dimer)

Molecular weight: 153.9

Synonyms: Sodium perborate tetrahydrate; sodium peroxoborate tetrahydrate; perboric acid, sodium salt, tetrahydrate

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Perborate Tetrahydrate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odorless, crystalline powder	4	EC (2007)
Melting Point	65°C	2	ECHA
Density	1.73 g/cm^3 @ 20°C	1	ECHA
Water Solubility	23.4 g/L @ 20°C (pH: ca. 10.1-10.4)	2	ECHA

The molecular crystalline structure of sodium perborate tetrahydrate consists of dimeric $[(HO)_2(BOO)]^-$ units which forms symmetric cyclic hexagonal anions with two peroxo

bridges each. In its crystalline form the substances are stable under dry conditions (EC, 2007).

In aqueous solutions at room temperature, an equilibrium occurs between sodium perborate and hydrogen peroxide (H_2O_2)/sodium metaborate ($NaBO_2$):

$NaBO_2(OH)_2 \bullet 3H_2O]_2 \Leftrightarrow 2NaBO_2 + 2H_2O_2 + 6H_2O$

At low concentrations (about $\leq$2 g/L), the equilibrium is largely on the side of the hydrolysis products; at high concentrations (about $\geq$12 g/L), the un-dissociated molecule is present in aqueous solutions. The hydrogen peroxide can be removed from the equilibrium by degradation to active oxygen, leading to an irreversible shift of the equilibrium to the degradation products sodium metaborate and water. This reaction is the basis of the bleaching effect of sodium perborate in the washing process (EC, 2007).

Sodium metaborate is the salt of a strong base (sodium hydroxide) and a weak acid (boric acid). So, sodium metaborate is expected to be present in aqueous solutions at environmental temperature and pH mainly as the weakly dissociated boric acid.

$NaBO_2 + 2H_2O \rightarrow Na^+ + OH^- + H_3BO_3$

H_3BO_3 (Boric acid) $\Leftrightarrow$ $[B(OH)_4]^-$ (borate) + H^+

Exposure to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. The B equivalents used are a generic designation rather than a designation of the element boron. The factor for converting sodium perborate tetrahydrate to B-equivalents is 0.07.

III. ENVIRONMENTAL FATE PROPERTIES

Many minerals contain boron, which is present as the sodium or calcium borate salt. Thus, boron is ubiquitous and widely distributed in the environment. It is present in rocks, soil and water and is released into the environment primarily from the weathering of rock and soil, volatilization of sea water, and anthropogenic activity.

The relative proportion of boric acid and borate ions is controlled by pH: $B(OH)_3 + 2H_2O \Leftrightarrow [B(OH)_4]^- + H_3O^-$. In dilute aqueous solutions, boric acid does not dissociate at pH <7; at pH values between 7 and 11, both boric acid and borate ions are present. In dilute aqueous solutions and physiological conditions, the predominant species present is un-dissociated boric acid. So, the consideration of boric acid addresses the relevant environmental stability properties for borates.

In natural waters, boron forms stable species and exists primarily as un-dissociated boric acid [$B(OH)_3$] and complex polyanions (*e.g.,* [$B(OH)_4]^-$) . These forms of boron are highly soluble and not easily removed from solution by natural mechanisms. Borate and boric acid are in equilibrium depending on the pH of the water. At an acidic pH, boron exists in solution mainly as un-dissociated boric acid, whereas at alkaline pH it is present as borate ions.

Degradation is not applicable to inorganic borates, such as sodium perborate tetrahydrate. It is not subject to hydrolysis, photodegradation, or biodegradation (ECHA). Inorganic borates are subject to chemical transformation processes (adsorption, complexation, precipitation, fixation) once released into the environment (ECHA).

The WHO review of boron (WHO, 1998) noted that "highly water soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as un-dissociated and highly soluble boric acid at neutral pH". A BCF of <0.1 was reported in Chinook salmon fed boron-supplemented diets for 60 to 90 days (Hamilton and Wiedmeyer, 1990). The hydrogen peroxide generated from the dissociation of sodium perborate tetrahydrate will be rapidly degraded by abiotic and biotic processes (EC, 2007).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium perborate tetrahydrate exhibits low acute toxicity by the oral and dermal routes; and slight-to-moderate acute toxicity by the inhalation route. It is not a skin irritant or sensitizer, but it is severely irritating to the eye. Toxicity studies on boric acid, borax (disodium tetraborate decahydrate), and boron oxide have been used to read-across to sodium perborate tetrahydrate. This is justified because, in aqueous media at physiological pH, all of these inorganic borate compounds will predominantly exist as un-dissociated boric acid. The developing fetus and the testes are the two most sensitive targets of boron toxicity in multiple species. The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic epithelium, impaired spermatogenesis, reduced fertility, and sterility. The developmental effects from boron exposure include high prenatal mortality; reduced fetal body weight; and malformations and variations. Repeated inhalation exposure to boron oxide resulted in slight irritation to the respiratory tract, but no systemic toxicity. Boric acid was not genotoxic; and boric acid and borax was not carcinogenic to rodents.

B. Acute Toxicity

The oral LD_{50} values of sodium perborate tetrahydrate in rats are 2,567 and 2,800 mg/kg (ECHA) [Kl. score = 1 and 2, respectively].

The 4-hour inhalation LC_{50} of sodium perborate tetrahydrate (as a dust) in rats is 1.17 mg/L. The MMAD ranged from 3.3 to 4.2 µm (ECHA) [Kl. score = 2].

There are no acute dermal toxicity studies on sodium perborate tetrahydrate. The dermal LD_{50} of sodium perborate monohydrate in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 1].

C. Irritation

Application of 0.5 g. sodium perborate tetrahydrate to the skin of rabbits for 4 hours under occlusive conditions was not irritating (ECHA) [Kl. score = 2].

Instillation of 0.1 mL sodium perborate tetrahydrate to the eyes of rabbits was considered corrosive (ECHA) [Kl. score = 2]. Another study showed that sodium perborate tetrahydrate was severely irritating to the eyes of rabbits (ECHA) [Kl. score = 2].

D. Sensitisation

No studies are available on sodium perborate tetrahydrate. In the mouse local lymph node assay (LLNA), sodium perborate monohydrate was not considered a skin sensitizer (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

<u>Oral</u>
Male and female Bor:WISW (SPFCpb) rats were dosed by oral gavage with 0 or 1,000 mg/kg sodium perborate tetrahydrate for 28 days. Clinical signs in the treated rats mainly consisted of salivation. There was no mortality. The treated males showed a 15% reduction in body weight gain and up to 15% reduction in feed consumption. There was possible treatment-related reduction in total cholinesterase and protein (both sexes) and albumin (males). Relative liver weights were slightly increased in the females. Histopathologic changes were reduction of parenchyma in the spleen (males); slight acathosis and hyperkeratosis in the forestomach (both sexes); and hyperplasia of the fundic mucosa (both sexes). There were no testicular effects in the treated males. The LOAEL for this study is 1,000 mg/kg-day; a NOAEL was not established (ECHA) [Kl. score = 2].

Male and female SD rats were given in their diet boric acid at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalent for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg-day, respectively (EPA, 2004).

By week 6, all of the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws, and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen ovary, and adrenal weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes, and adrenal weights. The adrenals of 4 of the 1,750 ppm males showed minor increases in lipid content and size of the cells in the zona reticularis. Atropied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. One 525 ppm male had partial testicular atrophy. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female SD rats were given in their diet borax at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalent for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg-day, respectively (EPA, 2004). By week 6, all of the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws, and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen and ovary weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes, and brain weights. The adrenals of the majority of the 1,750 ppm males and females showed slight to moderate increases in lipid content and size of the cells in the zona reticularis. Atropied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. Four 525 ppm males had partial testicular atrophy. Spermatogenic arrest was found in one 525 ppm male. NOAEL for this study is 175 ppm boron or 8.8 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female B6CF1_1 mice were given in the diet 0, 1,200, 2,500, 5,000, 10,000 or 20,000 ppm boric acid for 13 weeks (control and highest dose group) or 16 weeks (remaining dose groups). These dietary levels correspond to approximately 0, 34, 70, 141, 281 and 563 mg B/kg-day for males, respectively; and 0, 47, 97, 194, 388 and 776 mg B/kg-day for females, respectively (EPA, 2004). There was mortality (8/10 males; 6/10, females) in the 20,000 ppm, as well as hyperkeratosis and acanthosis. One male also died in 10,000 ppm group. Degeneration or atrophy of the seminiferous tubules occurred in the $\geq$5,000 ppm males. Minimal to mild extramedullary hematopoiesis of the spleen was observed in all dose groups. The LOAEL for this study is 1,200 ppm, corresponding to 34 and 47 mg B/kg-day for males and females, respectively (NTP 1987). [Kl. score = 2]

Male and female SD rats were given in their diet boric acid at doses of 0, 117, 350 or 1,170 ppm boric acid for two years. The average intake has been estimated to be approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively (EPA, 2004). The 1,170 ppm rats had decreased food consumption during the first 13 weeks of the study and suppressed growth throughout the study. Signs of toxicity in the 1,170 ppm animals

included swelling and desquamation of the paws, scaly tails, inflammation of the eyelids, and bloody discharge from the eyes. All of the 1,170 ppm males had testicular atrophy at the 6, 12 and 24 month time points. The seminiferous epithelium was atrophied, and the tubular size in the testes was decreased. There were significant decreases in the absolute and relative testes weights. Brain and relative thyroid weights were increased. The NOAEL for this study is 350 ppm B equivalents or 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

Male and female B6C3F_1 mice were given in their diet 0, 2,500 or 5,000 ppm boric acid in their feed for 103 weeks (NTP, 1987). These dose levels were equivalent to 0, 275 or 550 mg/kg-day boric acid or 0, 48 or 96 mg B/kg-day (EPA, 2004). There was reduced survival in the male mice, which was significantly different from the controls in the 2,500 ppm mice after week 63 and in the 5,000 ppm mice after week 84. The survival rates by the end of the study were 82, 60 and 44% in the 0, 2,500, and 5,000 ppm males, respectively; and 66, 66 and 74% in the 0, 2,500, and 5,000 ppm females, respectively. Mean body weights were 10-17% lower in the 5,000 ppm animals after 32 (males) or 52 (females) weeks compared to the controls There was testicular atrophy and interstitial cell hyperplasia in the testes of the 5,000 ppm males. A dose-related increase in the incidences of splenic lymphoid depletion in male mice was also observed. NTP considered this lesion to be associated with stress and debilitation, and it is reflected in the increased mortality in these groups of male mice. The NOAEL for this study is (NTP, 1987). [Kl. score = 2]

Inhalation

Male and female rats were exposed by inhalation to 0, 77, 175, or 470 mg/m^3 boron oxide. The exposures were 6 hours/day, 5 days/week for 24, 12, and 10 weeks for the 77, 175, and 470 mg/m^3 concentrations groups, respectively. The MMAD were 2.5, 1.9, and 2.4 µm for the 77, 175, and 479 mg/m^3 concentrations groups, respectively. There was no evidence of systemic toxicity. Some of the 470 mg/m^3 had reddish exudate from the nose. As these animals were covered with dust, this effect may have been local irritation of the nose and from the animals scratching the nose. The NOAEL for systemic toxicity is 470 mg/m^3, the highest exposure concentration tested. The NOAEL for localized effects (irritation) is 175 mg/m^3 (ECHA). [Kl. score = 2]

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on sodium borate tetrahydrate (or sodium perborate) are shown in Table 2. The in vitro genotoxicity studies on boric acid are shown in Table 3.

Table 2: *In vitro* Genotoxicity Studies on Sodium Perborate Tetrahydrate (or Sodium Perborate)

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* TA102 and TA2638; and *E. coli* WP2/pKM101 and WP2 *uvr*A/pKM101)	+**	NT	2	Watanabe et al. (1998)
Bacterial reverse mutation (*S. typhimurium* strains)	(-)TA98 (+) TA100, TA102	(-) TA98 (-) TA100, TA102	2	Seiler (1989)
Chromosomal aberrations (Chinese Hamster Ovary cells)	+	-	2	Seiler (1989)

*+, positive; -, negative; NA, not applicable; NS, not specified; NT, not tested.
**Two independent laboratories.

Table 3: *In vitro* Genotoxicity Studies on Boric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Chromosomal aberrations (Human peripheral lymphocytes)	NS	+	2	ECHA
Unscheduled DNA synthesis (rat liver cells)	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable; NS, not specified.

The genotoxic potential of sodium perborate in the absence of metabolic activation may be due to the generation of hydrogen peroxide. If so, then the results from the *in vitro* tests may not be relevant *in vivo* because hydrogen peroxide is readily reduced by catalase. Boric acid, the other dissociated product from sodium perborate tetrahydrate (or sodium perborate) did not show any genotoxic potential in any of the *in vitro* tests.

In Vivo Studies

No studies are available on sodium perborate tetrahydrate.

Male and female Swiss Webster mice were given two daily doses of 0, 225, 450, 900, 1,800, or 3,500 mg/kg boric acid. The frequency of micronucleated polychromatic erythrocytes were not increased at any dose level (ECHA) [Kl. score = 1].

G. Carcinogenicity

Oral

No studies have been conducted on sodium perborate tetrahydrate.

Male and female SD rats were given in their diet disodium tetraborate decahydrate (borax) or boric acid at doses of 0, 117, 350, or 1,170 ppm as Boron equivalents (approximately 0, 5.9, 17.5, or 58.5 mg B/kg-day) for two years. There was no mention of tumors in the report. Nevertheless, NTP (1987) concluded that this study provided adequate data on the lack of carcinogenic effects of boric acid in rats (Weir and Fisher, 1972; EPA, 2004).

Male and female B6C3F_1 mice were given in their diet 0, 2,500, or 5,000 ppm boric acid for 103 weeks. The dietary levels are equivalent to 0, 446, or 1,150 mg/kg-day boric acid or 0, 78.1, or 201.3 mg B/kg-day. There was no evidence of carcinogenicity (NTP, 1987). [Kl. score = 2]

H. Reproductive Toxicity

A three-generation reproductive toxicity study was conducted in albino rats (strain not specified) with boric acid. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170 ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

A three-generation reproductive toxicity study was conducted in albino rats (strain not specified) with disodium tetraborate decahydrate. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg-day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170 ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg-day (Weir and Fisher, 1972). [Kl. score = 2]

In a continuous breeding protocol, male and female CD-1 mice were given in their diet 0, 1,000, 4,500 or 9,000 ppm boric acid in their feed. The authors estimated that the average daily intakes were: 0, 26.6, 111, and 220 mg B/kg-day to males; and 0, 31.8, 152, 257 mg B/kg-day to females. Boric acid consumption did not differ among the groups. There were no litters in the 9,000 ppm breeding pairs. At 4,500 ppm, there was a successful first litter, after which there was a progressive decrease in fertility; only one pair produced a fourth and fifth litter. All fertility indices were affected in the 4,500 ppm group. A complete crossover mating trial was conducted using control mice and the 4,500 ppm mice. The results showed that the probable cause of the reduced fertility was a decrement in male fertility. A dose-related decrease in body, testicular and epididymal weights was observed in the 4,500 and 9,000 ppm F_0 males. Sperm count was significantly decreased in these two dose groups, and percent motile sperm was decreased in all dose groups. Testicular histopathology showed seminiferous tubular atrophy in the 9,000 ppm males and partial atrophy of the seminiferous tubules in the 4,500 ppm males. There were no histopathologic changes in the 4,500 ppm females. No statistically significant decreases in mating index, fertility index, or live pups/litter in

the 4,500 ppm females, but the number of days to litter in this dose group was increased. Estrous cyclicity was unaffected. Reproductive organ weights were unaffected, but relative maternal liver and kidney/adrenal weights were reduced. An F_1 fertility trial was performed using offspring from the 1,000 ppm groups. There was no decreases in mating, fertility or reproductive performance. The F_2 adjusted live pup weight was slightly, but significantly, reduced from controls. A clear NOAEL for reproductive toxicity in males was not seen in this study. The 1,000 ppm males had decreased sperm motility in the F_0 generation and decreased sperm concentration in the F_1 generation. Decreased F_2 pup relative body weight was statistically significant from controls. The NOAEL in this study for females is 1,000 ppm boric acid or 32 mg B/kg-day). The LOAEL in this study for males is 1,000 ppm or 27 mg B/kg-day; a NOAEL was not established (Fail *et al.* 1991). [Kl. score = 2]

I. Developmental Toxicity

Pregnant female Crl:CD(SD)BR rats were dosed by oral gavage with 0, 100, 300, or 1,000 mg/kg sodium perborate tetrahydrate during gestational days 6 to 15. Maternal body weight gain and feed consumption were significantly reduced in the ≥300 mg/kg dose groups. A dose-related increase was seen in resorptions, placental weights, and fetal body weights in the 300 and 1,000 mg/kg dose groups. Malformations (mainly related to the skeletal and to the cardiovascular system) were increased in the 1,000 mg/kg dose group. The NOAEL for maternal and developmental toxicity is 100 mg/kg-day (ECHA). [Kl. score = 1]

Pregnant female SD rats were given 0, 0.1, 0.2 or 0.4% boric acid in their feed on gestational days (GD) 0 to 20 or 0.8% boric acid on GD 6 to 15. The average amounts of boric acid ingested were estimated to be 0, 78, 163, 330 or 539 mg/kg-day (0, 13.6, 28.5 or 57.7 mg B/kg-day), respectively. Effects on the dams were altered food and/or water intake at ≥0.2% boric acid, increased liver and kidney weights relative to body weights at ≥0.2%, reduced weight gain at ≥0.4%, and increased corrected weight gain at 0.4% boric acid. There was a reduction in fetal body weights in all treated groups (94, 87, 63, and 47% of control weight, respectively). Increased malformations occurred at ≥0.2% and prenatal mortality was increased at 0.8%. There was a dose-response for altered skeletal morphology in rats (≥0.1%), and specific findings were significantly elevated above controls at ≥0.2%. Specifically, there was an increased incidence of short rib XIII (a malformation) and a decreased incidence or rudimentary or full rib(s) at lumbar I (an anatomical variation) (Heindel *et al.* 1992). [Kl. score = 2]

Pregnant female SD rats were given in their feed 0, 0.025, 0.005, 0.075, 0.1 or 0.2% boric acid on GD 0 to 20. Approximately half of the dams were terminated on GD 20, and the remaining dams delivered their litters. Pup growth and viability were monitored until postnatal day (PND) 21. The average amounts of boron ingested on GD 20 were: 0, 3.3, 6.3, 9.6, 13.3, and 25 mg B/kg-day], respectively. The average amounts of boron ingested on PND 21 were : 0, 3.2, 6.5, 9.7, 12.9, and 25.3 mg B/kg-day,

respectively. There were no maternal deaths and no treatment-related clinical signs. Maternal body weights were similar across all groups during gestation. However, decreased maternal body weights (GD 19 and 20 at sacrifice) and decreased maternal body weight gain (GD 15-18 and GD 0-20) were statistically significant in trend tests. There was a 10% reduction in gravid uterine weight (statistically significant) in the 0.2% group. Corrected maternal weight (maternal gestational weight minus reduced gravid uterine weight) was unaffected by treatment. Feed intake in the 1,000 ppm dams was minimally affected and only during the first three days of dosing. Water consumption was higher in the treated groups after GD 15. The number of corpora lutea and uterine implantation sites, and the percentage of preimplantation loss were similar across all groups. Increased relative kidney weights were increased in the 0.2% group. There were no differences in the viability of the offspring between treated and controls. On GD 20, fetal body weight was 94% and 88% of controls in the 0.1% and 0.2% groups, respectively; recovery was complete at birth (~GD 22). The incidence of short rib XIII was increased on GD 20 in the $\geq$0.1% groups, but only in the 0.2% group at PND 21. The incidence of wavy rib was increased on GD 20 in the $\geq$0.1% group; the reversibility of this effect was confirmed on PND 21. There was a slight decrease in extra lumbar ribs in the 0.2% group on GD 20, and extra lumbar ribs were seen in the 0.2% group on PND 21. The developmental NOAEL was considered to be 0.075% boric acid or 9.6 mg B/kg-day on GD 20; and 0.1% boric acid or 12.9 mg B/kg-day on PND 21 (Price *et al.* 1996a). [Kl. score = 1]

Pregnant Swiss mice were given in their diet 0, 0.1, 0.2 or 0.4% boric acid on gestational days (GD) 0 to 17. The average amounts of boric acid ingested were estimated to be 248, 452 or 1,003 mg/kg-day (0, 43.4, 79.0 or 175.3 mg/B/kg-day), respectively. Maternal toxicity consisted of mild kidney lesions ($\geq$0.1%), increased water intake and relative kidney weights (0.4%), and decreased water intake during treatment. Fetal body weights were reduced in the $\geq$0.2% groups, and there were increased incidences of resorptions and malformed fetuses per litter in the 0.4% group. The LOAEL for maternal toxicity is 248 mg/kg-day boric acid or 43.4 mg B/kg-day; a NOAEL was not established. The NOAEL for developmental toxicity is 248 mg/kg-day boric acid or 43.4 mg B/kg-day (Heindel *et al.* 1992). [Kl. score = 2]

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 62.5, 125 or 250 mg/kg boric acid (0, 10.9, 21.9 or 43.7 mg B/kg) during GD 6-19. Feed intake was in the 250 mg/kg maternal animals during the exposure period, but it was increased in the $\geq$125 mg/kg dose groups. In the 250 mg/kg group, maternal body weights during GD 9-30, weight gain during GD 6-19, gravid uterine weight, and number of corpora lutea per dam were significantly reduced.
In the $\geq$125 mg/kg groups, maternal corrected gestational weight gain was increased compared to controls. Maternal liver weights were unaffected by treatment. In the 250 mg/kg group, relative, but not absolute, kidney weights were increased, although no effects in the kidney were noted in the histopathological examination. Prenatal mortality was increased in the 250 mg/kg group (90% resorptions/litter versus 6% for

controls); the proportion of pregnant females with no live fetuses was increased (73% versus 0%), and live litter size was reduced (2.3 fetuses versus 8.8). Thus, there were only 14 live fetuses (6 live litters) available for evaluation in the 250 mg/kg group. The percentage malformed fetuses/litter was increased in the 250 mg/kg group, primarily due to cardiovascular defects (72% versus 3% of controls). There was no definitive maternal or developmental toxicity in the 62.5 or 125 mg/kg dose groups. The NOAEL for maternal and developmental toxicity is 125 mg/kg-day boric acid or 21.9 mg B/kg-day (Price *et al.* 1996b). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for disodium octaborate tetrahydrate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The developing fetus and the testes are the two most sensitive targets of boron toxicity in multiple species (EPA, 2004; ECHA, 2010). The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic epithelium, impaired spermatogenesis, reduced fertility, and sterility (EPA, 2004). The developmental effects from boron exposure include high prenatal mortality; reduced fetal body weight; and malformations and variations (EPA, 2004).

The U.S. Environmental Protection Agency (U.S. EPA) derived an Oral Reference Dose (RfD) for boron of 0.2 mg B/kg-day (U.S. EPA 2004) based on developmental effects in rats from two studies (Price *et al.* 1996a; Heindel *et al.* 1992).

The RfD was derived using the benchmark dose (BMD) method ($BMDL_{05}$ from Allen *et al.* 1996) using a data derived uncertainty factor of 66. Decreased fetal body weight ($BMDL_{50}$ = 59 mg boric acid/kg-day or 10.3 mg B/kg-day) was considered by Allen *et al.* (1996) as the most suitable endpoint for developing a point of departure, because the benchmark doses calculated for the other endpoints (incidence of total malformations, enlarged lateral ventricles in the brain, shortening of rib XIII, and variations of the first lumbar rib) were higher.

Derivation of an Oral Reference Dose

Oral RfD = $BMDL_{05}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10.42 [3.16, toxicodynamics; 3.3, toxicokinetics]
UF_H (intraspecies variability) = 6.32 [3.16, toxicodynamics; 2.0, toxicokinetics]
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 10.3/(7.9 x 6.3 x 1 x 1 x 1) = 10.3/66 = 0.2 mg B/kg-day

Derivation of a drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.2 x 70 x 0.1)/2 = 0.7 mg/L

Australian drinking water guideline

The Australian drinking water guideline for boron is 4 mg/L (ADWG, 2011).

B. Cancer

There was no evidence of carcinogenicity in rat and mouse chronic studies conducted on disodium tetraborate decahydrate and/or boric acid. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium perborate tetrahydrate does not exhibit the following physico-chemical properties (ECHA):

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Aquatic Toxicity

The summary of the data used by ANZECC to develop a water quality guideline for boron is as follows:

Freshwater Fish
The chronic values for four species ranged from 40 µg/L (32-day LOEC in *O. mykiss*) to 27,600 µg/L (32-day LOEC in *O. mykiss*). Other *O. mykiss* data were order of magnitude higher than 40 µg/L, including those from the same paper, including those from the same paper (2,100 µg/L for a 87-day NOEC and 27,600 µg/L for a 32-day LC_{50}). All other geometric means were >4,000 µg/L.

Freshwater Crustaceans
The chronic data ranged from a 21-day MATC value of 4,665 µg/L for *Daphnia magna* based on growth to an LC_{50} value of 54,200 µg/L from a 21-day *Daphnia* study. A measured NOEC of 6,000 µg/L based on reproduction was also reported.

Freshwater Algae
The data ranged from a 14-day NOEC of 400 µg/L for *Chlorella pyrenoidosa* to a NOEC of 5,200 µg/L for *Chlorella vulgaris*. Both values are based on population growth.

C. Terrestrial Toxicity

There are considerable number of terrestrial toxicity studies on borates. See disodium tetraborate, anhydrous in the ECHA REACH database (ECHA) for the summaries of the relevant studies on borates.

D. Calculation of PNEC

PNEC water
The ANZECC water quality guideline (2000) used a "freshwater high reliability trigger value for boron of 370 µg/L was calculated using the statistical distribution method at 95% protection."

"Although the 95% protection level is higher than the 32-day LOEC of 100 µg/L for O. mykiss, this figure appeared anomalous and other data on this species showed much less toxicity. The low figure may need to be checked. The 95% figure is considered sufficiently protective for slightly-moderate disturbed ecosystems" (ANZECC, 2000).

PNEC sediment
No experimental toxicity data on sediment organisms are available. Sodium perborate tetrahydrate dissociates completely in water and its environmental distribution is

dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, especially those subject to chemical dissociation, such as sodium perborate tetrahydrate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on the its properties, no adsorption of sodium perborate tetrahydrate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC Soil

In the ECHA REACH database (ECHA), a $PNEC_{soil}$ was derived for boron using the species sensitivity distribution method and an assessment factor of 2. The $PNEC_{soil}$ was determined to be 5.7 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium perborate tetrahydrate is an inorganic compound that dissociates completely to boric acid and the borate anion in aqueous media. Biodegradation is not applicable to these inorganic compounds; both boric acid and borate are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium perborate tetrahydrate.

Sodium perborate tetrahydrate is a water-soluble substance that is not expected to bioaccumulate. Limited data indicate that bioaccumulation (BCF values are low) is not significant in aquatic and terrestrial food chains. Thus, it does not meet the criteria for bioaccumulation.

Boric acid and inorganic borates are reproductive toxicants and have been classified under GHS as known or presumed human reproductive toxicants (Category 1B). Thus, sodium perborate tetrahydrate meets the PBT criteria of toxicity.

Therefore, sodium perborate tetrahydrate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Inhalation]
Eye Damage Category 1
Reproductive Toxicant Category 1B
STOT SE Category 3 [Respiratory irritation]

In addition to the hazard statements corresponding the GHS classifications, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger
According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child, causes serious eye damage, is harmful if swallowed, is harmful if inhaled, is suspected of damaging fertility or the unborn child, may cause respiratory irritation and causes skin irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water. Do not induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
None identified.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eye, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage and Handling

General Handling
No special measures necessary provided product is used correctly.

Other Handling Precautions
Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids, or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for sodium perborate tetrahydrate.

Engineering Controls
Ensure adequate ventilation. Localized ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment

Respiratory Protection:
Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium perborate tetrahydrate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Allen, B.C., Strong, P.L., Price, C.J., Hubbard, S.A., and Daston, G.P. (1996). Benchmark dose analysis of developmental toxicity in rats exposed to boric acid. Fundam. Appl. Toxicol. 32: 194-204.

ANZECC (2000). Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Volume 2, Aquatic Ecosystems – Rationale and Background Information, Australian and New Zealand Environment and Conservation Council (ANZECC) and Agriculture and Resource Management Council of Australia and New Zealand.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

ECHA (2010). Member state committee draft support document for identification of boric acid as a substance of very high concern because of its CMR properties. Available at: https://echa.europa.eu/documents/10162/d51fd473-40ec-4831-bc2d-6f53bdf9cbbe.

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fail, P.A., George, J.D., Seely, J.C., Grizzle, T.B., and Heindel, J.J. (1991). Reproductive toxicity of boric acid in Swiss (CD-1) mice: assessment using the continuous breeding protocol. Fundam. Appl. Toxicol. 17: 225-239.

Hamilton, S.J., and Wiedmeyer, R.H. (1990). Concentrations of boron, molybdenum and selenium in chinook salmon. Trans. Amer. Fisheries Soc. 119: 500-510.

Heindel, J.J., Price, C.J., Field, E.A., Marr, M.C., Myers, C.B., Morrissey, R.E., and Schwetz, B.A. (1992). Developmental toxicity of boric acid in mice and rats. Fundam. Appl. Toxicol. 18: 266-272.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

National Toxicology Program [NTP] (1987). Toxicology and Carcinogenesis Studies of Boric Acid (CAS No. 10043-35-3) in B6C3F$_1$ Mice. NTP TR 324, NIH Publication No. 88-2580. National Toxicology Program, U.S. Department of Health and Human Services, National Institute of Health.

Price, C.J., Strong, P.L., Marr, M.C., Myers, C.B., and Murray, F.J. (1996a). Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. Fundam. Appl. Toxicol. 32: 179-193.

Price, C.J., Marr, M.C., Myers, C.B., Seely, J.C., Heindel, J.J., and Schwetz, B.A. (1996b). The developmental toxicity of boric acid in rabbits. Fundam. Appl. Toxicol. 34: 176-187.

Seiler, J.P. (1989). The mutagenic activity of sodium perborate. Mutat. Res. 224: 219-227.

U.S. EPA (2004). U.S. EPA (United States Environmental Protection Agency). Integrated Risk Information System (IRIS) – Boron and Compounds; CASRN 7440-42-8. Available at: http://www.epa.gov/iris.

Watanabe, K., Sakamoto, K., and Sasaki, T. (1998). Comparison on chemically-induced mutation among four bacterial strains, *Salmonella typhimurium* TA102 and TA2638, and *Escherichia coli* Wp2/pKM101 and WP2 *uvr*A/pKM101: collaborative study II. Mutat. Res. 412: 17-31.

Weir, R.J., Jr., and Fisher, R.S. (1972). Toxicologic studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

WHO (1998). Environmental Health Criteria 204, Boron, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland.

SODIUM PERSULFATE

This dossier on sodium persulfate presents the most critical studies pertinent to the risk assessment of sodium persulfate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Disodium [(sulfonatoperoxy)sulfonyl]oxidanide

CAS RN: 7775-27-1

Molecular formula: $O_8S_2.2Na$

Molecular weight: 238.1

Synonyms: Sodium persulfate; disodium persulfate; sodium peroxodisulfate; disodium [(sulfonatoperoxy)sulfonyl]oxidanide

SMILES: [O-]S(=O)(=O)OOS(=O)(=O)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Persulfate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, crystalline, odorless solid	1	ECHA
Melting point	Decomposes at 180°C before melting point is reached.	1	ECHA
Density	1.68 g/cm^3	1	ECHA
Vapor pressure	Negligible	2	ECHA
Partition coefficient (log K_{ow})	Not applicable	-	-
Water solubility	Very soluble	2	ECHA
Oxidizing properties	Strong oxidizer	4	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Sodium persulfate dissociates in aqueous media to the sodium cation (Na^+) and persulfate anion ($S_2O_8^{2-}$) (OECD 2005a; ECHA). The persulfate anion will readily hydrolyze (decompose) into sulfate ions.

The rates of hydrolysis are expected to be similar for sodium persulfate, potassium persulfate, and ammonium persulfate. The rates of decomposition (hydrolysis) was measured at 50°C at various pHs. The half-lives increased from 20 hours at pH 1 to 210 hours at pH 10 (Koltoff and Miller, 1951).

Biodegradation is not applicable to inorganic compounds. Sodium persulfate is not expected to bioaccumulate; it will dissociate (and decompose) to ions that are ubiquitous in the environment. Sodium persulfate is not expected to absorb to soil or sediment because of its dissociation properties, instability (hydrolysis), and high water solubility.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium persulfate exhibits moderate acute toxicity by the oral route, and low acute toxicity by the inhalation and dermal routes. In humans, sodium persulfate has the potential for skin irritation; it is also a skin sensitizer to guinea pigs and humans. Human exposure to persulfates (including sodium persulfate) have been linked to a variety of skin and respiratory complaints indicative of sensitization. The complaints consist of immediate and delayed contact hypersensitivity, contact urticarial, rhinitis, bronchitis, and asthma. Repeated oral exposure to sodium persulfate resulted in irritation to the gastrointestinal tract; and respiratory irritation was seen in rats repeatedly exposed by inhalation to ammonium persulfate. Sodium persulfate is not genotoxic. A dermal carcinogenicity study showed no carcinogenic effects in mice. In a screening study, there was no reproductive or developmental toxicity in rats given oral gavage doses of ammonium persulfate.

B. Acute Toxicity

The oral LD_{50} in male rats is 895 mg/kg (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} of sodium persulfate dust is >5.1 mg/L. The mass median aerodynamic diameter (MMAD) ranged from 4.28 to 5.35 µm. The fraction of particles $\leq$1 µm in MMAD ranged from 0 to 5.6%. The fraction of particles $\leq$10 µm in MMAD ranged from 76.5 to 81.2% (ECHA) [Kl. score = 1].

The dermal LD_{50} in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 1].

C. Irritation

Application of 0.5 mL of sodium persulfate (aqueous solution) to the skin of rabbits for 4 hours under occlusive conditions was not irritating (ECHA) [Kl. score = 1]. In another study, application of sodium persulfate to the skin of rabbits was not irritating (ECHA) [Kl. score = 2].

Instillation of sodium persulfate into the eyes of rabbits was slightly irritating. Slight conjunctival effects were noted in five of six animals; all observed effects were completely reversible within 24 hours (ECHA) [Kl. score = 2].

Studies in humans indicate that persulfates have the potential for skin irritation (NICNAS, 2001). Calnan and Schuster (1963) reported skin irritation in a human patch test with 5% ammonium persulfate. Jordan (1998) reported that a mixture with 17.5% persulfates (ammonium, potassium, and sodium) induced skin irritation in human subjects from patches applied under occlusive conditions.

D. Sensitization

Sodium persulfate was a skin sensitizer when tested in a guinea pig maximization test. The concentration of sodium persulfate used in the induction and challenge phases was 0.1% in physiological saline (ECHA) [Kl. score = 1]. Sodium persulfate was not a skin sensitizer to guinea pigs in a Buehler test (dermal application only). The concentration of sodium persulfate used for the induction and challenge phase was 0.3 g (ECHA) [Kl. score = 1].

Sodium persulfate was considered a strong skin sensitizer in a mouse local lymph node assay (ECHA) [Kl. score = 1].

Human exposure to persulfates has been linked to a variety of skin and respiratory complaints indicative of sensitization. The complaints consist of immediate and delayed contact hypersensitivity, contact urticarial, rhinitis, bronchitis, and asthma (NICNAS, 2001).

E. Repeated Dose Toxicity

Oral

Male and female CR strain rats were fed in their diet 0, 300, 1,000 or 3,000 ppm sodium persulfate for 90-days. On day 48 of the study, the dietary concentration of the group receiving 1,000 ppm was increased to 5,000 ppm for the remainder of the study. Body weights was decreased in the two highest dose groups during the last six weeks of treatment. There were no treatment-related effects on urinalysis, clinical chemistry or hematology parameters. Histopathological findings were limited to the 3,000 ppm group only and consisted of necrosis and atrophy of the gastrointestinal tract epithelial lining. The absence of the gastrointestinal lesions in the group receiving 1,000 ppm for 8 weeks, followed by 5000 ppm for 5 weeks, indicates that the lesions are related both to concentration in diet (dose) and length of exposure. A clear NOAEL for this study is 300 ppm, which is estimated to be 22 mg/kg-day. Another NOAEL may be the 1,000 ppm dietary group for an 8-week exposure period. (ECHA; OECD, 2005a,b). [Kl. score = 2]

Inhalation

No studies are available on sodium persulfate.

Male and female SD rats were exposed (whole-body) by inhalation to 0, 5, 10.3, or 25 mg/m^3 ammonium persulfate dust, 6 hours/day, 5 days/week for 13 weeks. Additional groups of animals were exposed for 13 weeks, followed by either a 4- or 13-week recovery period. The MMAD was 2.5, 2.7, and 2.5 µm for the 5, 10, and 25 mg/m^3 groups, respectively. No deaths occurred during the study that were considered to be exposure-related. The 25 mg/m^3 animals showed increased respiration rates, as well as a few of the 25 mg/m^3 animals. This clinical sign disappeared during the first few weeks of the recovery period. Body weights of the 25 mg/m^3 animals were significantly lower during most of the exposure period; by the end of the recovery period the body weights were comparable to the controls. Lung weights were increased in the 25 mg/m^3 animals at the end of the 13-week exposure period but were similar to controls after 6 weeks in the recovery period. Histopathologic changes indicative of irritation was seen in the trachea and bronchi/bronchioles in the 25 mg/m^3 animals; these lesions were not seen after 6 weeks in the recovery period. The NOAEL for this study is 10.3 mg/m^3 (ECHA). [Kl. score = 1]

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on sodium persulfate are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Sodium Persulfate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	ECHA
Unscheduled DNA synthesis (rat hepatocytes)	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable

In vivo Studies

Sodium persulfate did not induce micronuclei in the bone marrow cells of male and female mice given a single intraperitoneal injection of 0, 85, 169, or 338 mg/kg sodium persulfate (ECHA) [Kl. score = 2].

G. Carcinogenicity

No studies are available on sodium persulfate.

A 51-week dermal study in female SENCAR mice exposed to 0.2 ml of a 200 mg/mL solution of ammonium persulfate showed that ammonium persulfate is neither a tumor promoter nor a complete carcinogen when applied to the skin (OECD, 2005a,b; ECHA). [Kl. score = 2]

H. Reproductive and Developmental Toxicity

No studies are available on sodium persulfate.

A reproductive and developmental toxicity screening study (OECD 421) has been conducted on ammonium persulfate. Male and female Crl:CD (SD)GS BR rats were fed in their diet 0, 40, 100, or 250 mg/kg ammonium persulfate. In the parental animals, there was no treatment-related mortality, clinical signs, body or organ weight changes, or effects seen in gross necropsy. There were no effects on reproductive performance, fertility, fetal anomalies, fetal viability, spermatogenesis, spermatogenic cycle. The NOAEL for reproductive and developmental toxicity and parental toxicity is 250 mg/kg-day, the highest dose tested (ECHA). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived. Sodium persulfate dissociates in water to sodium and persulfate ions. The persulfate ions will further hydrolyze to sulfate ions.

The Australian drinking water guideline value for sodium is 180 mg/L based on aesthetics (ADWG, 2011).

The Australian drinking water guideline value for sulfate is 500 mg/L based on health. Concentrations of >500 mg/L can have purgative effects. There is also an Australian drinking water guideline value for sulfate of 250 mg/L based on aesthetics; it is the taste threshold (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium persulfate is an oxidizing solid.

Sodium persulfate does not exhibit the following physico-chemical properties:
- Explosivity
- Flammability

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium persulfate has a low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies on sodium persulfate.

Table 3: Acute Aquatic Toxicity Studies on Sodium Persulfate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-h LC_{50}	163	1	ECHA
Daphnia magna	48-h EC_{50}	133	1	ECHA
Selenastrum capricornutum	72-h EC_{50}	116	1	ECHA

Chronic Studies
No data are available.

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for sodium persulfate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (163 mg/L), *Daphnia* (133 mg/L), and algae (116 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported effect concentration of 116 mg/L for algae. The $PNEC_{water}$ is 1.2 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. Sodium persulfate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium persulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on the its properties, no adsorption of sodium persulfate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on terrestrial organisms are available. The environmental distribution of sodium persulfate is dominated by its water solubility. Sorption of sodium persulfate should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{oc} and K_{ow} parameters do not readily apply to inorganics, such as sodium persulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on the its properties, sodium persulfate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium persulfate is an inorganic compound that dissociates completely to sodium and persulfate ions in aqueous solutions. Persulfate ions are further hydrolysed to sulphate

ions. Biodegradation is not applicable to these compounds. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium persulfate or its dissociated compounds.

Sodium persulfate is an inorganic compound that dissociates completely in water to ionic compounds that are ubiquitous in the environment. Thus, sodium persulfate is not expected to bioaccumulate.

There are no chronic aquatic toxicity data on sodium persulfate. The acute E(L)C_{50} values for fish, invertebrates, and algae are >1 mg/L. Thus, sodium persulfate does not meet the screening criteria for toxicity.

Therefore, sodium persulfate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Oxidizing Solid Category 3
Acute Toxicity Category 4 [Oral]
Skin Irritant Category 2
Eye Irritant Category 2
Skin Sensitizer Category 1
Respiratory Sensitization Category 1
STOT SE Category 3 [Respiratory Irritation]

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: sulfur oxides.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eye, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage and Handling

General Handling

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Other Handling Precautions
Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids, or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for sodium persulfate in Australia is 0.01 mg/m^3 as a peak exposure. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls
Ensure adequate ventilation. Localized ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment
Respiratory Protection:
Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible. Remove and wash contaminated clothing before re-use. Contaminated work clothing should not be allowed out of the workplace.

F. Transport Information

UN1505 SODIUM PERSULPHATE
Class: 5.1
Packing Group: III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Calnan, C.D., and Shuster, S. (1963). Reactions to ammonium persulfate. Arch. Dermatol. 46: 812-815.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Jordan, W.P. (1998). Human sensitization study of three persulfates in a representative vehicle used for bleaching hair. Unpublished data submitted to CFFA; cited in Pang and Fiume (2001).

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Koltoff, I., and Miller, I.K. (1951). The chemistry of persulfate. I. The kinetics and mecanism of the decomposition of the persulfate ion in aqueous medium. J. Am. Chem. Soc. 73: 3055-3059.

National Industrial Chemicals Notification and Assessment Scheme [NICNAS] (2001). Ammonium, Potassium and Sodium Persulfate. Priority Existing Chemical Assessment Report No. 18. Available at: https://www.nicnas.gov.au/chemical-information/pec-assessments.

OECD (2005a). IUCLID Data Set for Ammonium persulfate (CAS No. 7727-54-0); Potassium persulfate (CAS No. 7727- 27-1); Sodium persulfate (CAS No. 7775-27-1), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=5D4B16BE-8BA8-4BE4-8787-469DE31A76E9.

OECD (2005b). Screening Information Dataset (SIDS) Initial Assessment Report for Ammonium persulfate (CAS No. 7727-54-0); Potassium persulfate (CAS No. 7727-27-1); Sodium persulfate (CAS No. 7775-27-1), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=5D4B16BE-8BA8-4BE4-8787-469DE31A76E9.

Pang, S., and Fiume, M.Z. (2001). Cosmetics Ingredient Review: Final Report on the Safety Assessment of Ammonium, Potassium, and Sodium Persulfate. Intl. J. Toxicol. 20(Suppl 3): 7-21.

SODIUM POLYACRYLATE

This dossier on sodium polyacrylate presents the most critical studies pertinent to the risk assessment of sodium polyacrylate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the HERA document on polyacrylic acid homopolymers and their sodium salts (CAS 9003-04-7) (HERA, 2014). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 1-Propenoic acid, homopolymer, sodium salt

CAS RN: 9003-04-7

Molecular formula: $(C_3H_4O_2)x$-.x-Na

Molecular weight: Variable

Synonyms: 2-Propenoic acid, homopolymer, sodium salt; polyacrylic acid, sodium salt, sodium polyacrylate; acrylic acid, polymers, sodium salt; poly(acrylic acid), sodium salt; polyacrylate sodium salt

II. PHYSICAL AND CHEMICAL PROPERTIES

Sodium polyacrylates are polymers that range in molecular weight (MW) from 1,000 to 78,000 (HERA, 2014). The sodium polyacrylates mostly used in detergents have a typical molecular weight of approximately 4,500 (HERA, 2014). For sodium polyacrylate (MW 4,500), the melting point is >150°C, where is decomposes; and the water solubility is >400 g/L (HERA, 2014).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Sodium polyacrylates are not readily biodegradable. Due to their high molecular weights, sodium polyacrylates are not expected to bioaccumulate. In addition, these water-soluble polymers can form insoluble calcium salts in natural waters, suggesting that bioaccumulation is unlikely.

B. Abiotic Degradation

Abiotic degradation mechanisms, such as photolytic and hydrolytic processes, do not significantly influence the environmental fate of sodium polyacrylates (HERA, 2014).

C. Biodegradation

Sodium polyacrylates are not readily biodegradable, but are partly accessible to ultimate biodegradation particularly under long incubation conditions. Sodium polyacrylates with MW of <2,000 are partly biodegradable under the conditions of soil and sediment inoculation. Test results with activated sludge inoculum indicate different elimination degrees, apparently due to adsorption and precipitation processes. The removal degrees of different sodium polyacrylates show no clear relationship between elimination extent and molecular weight (HERA, 2014).

D. Bioaccumulation

No experimental studies are available on sodium polyacrylates. Estimated bioconcentration factors based on octanol-water coefficients are not appropriate since the molecular weights of these polymers are higher than the molecular weight range for the QSAR models. Due to their high molecular weights, sodium polyacrylates are not expected to bioaccumulate. In addition, these water-soluble polymers can form insoluble calcium salts in natural waters, suggesting that bioaccumulation is unlikely.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of sodium polyacrylates are very low by the oral and dermal routes. These polymers are not irritating to the skin and eyes; nor are they skin sensitizers. No systemic toxicity was observed in rats given high oral doses of a sodium polyacrylate for four weeks; pulmonary irritation was seen in rats that inhaled an aerosol or dust of a sodium polyacrylate for 13 weeks, but there was no systemic toxicity. No developmental toxicity was seen in rats when given high oral doses of sodium polyacrylates. Sodium polyacrylates are not genotoxic.

B. Acute Toxicity

Acute oral toxicity studies have been conducted in rats on sodium polyacrylates with molecular weights (MW) of 1,000 to 78,000. The oral LD_{50} values are >5,000 or >10,000 mg/kg (the highest doses tested), with the exception of one study on a 3,500 MW sodium polyacrylate, which was reported to be >1,000 mg/kg (the attainable limit dose of a 10% aqueous solution) (HERA, 2014). [Kl. scores = 2]

The dermal LD_{50} values in rabbits for sodium polyacrylates with MW of 1,000 or 4,500 are >5,000 mg/kg (HERA, 2014). [Kl. scores = 2]

No acute inhalation studies are available.

C. Irritation

According to (HERA, 2014) sodium polyacrylates with MW of 1,000 to 78,000 are not irritating to the skin or eyes [Kl. scores = 2]. However, as per ECHA current classification, the substance 2-Propenoic acid, homopolymer, sodium is considered a skin and eye irritant. Thus, this classification will be retained for purposes of this dossier.

D. Sensitisation

Sodium polyacrylates with MW of 4,500 or 78,000 were not dermal sensitizers in the guinea pig maximization test (HERA, 2014). [Kl. scores = 2 and 4, respectively]

E. Repeated Dose Toxicity

Oral

Male rats were fed diets containing 0 or 2.5% sodium polyacrylate (MW 2,500) for four weeks. Body weight, body weight gain, and appearance of the animals were similar between treated and control animals. In the fourth week of the study, a small, but significant, decrease in total weight of bone minerals was detected and confirmed by radiographic and histological examination. There was a

significant reduction in the concentration of magnesium in the bones and plasma of the treated animals. Calcium loss was slight and not statistically significant. Urinary excretion of sodium and phosphorus was markedly increased; calcium only slightly increased. The authors of the study interpreted the finding as a metabolic imbalance rather than systemic toxicity. Sodium excretion could have been increased by the high intake of the sodium-neutralized test substance. The NOAEL for the study was considered to be 2.5% sodium polyacrylate in the diet, which was estimated to be 1,136 mg/kg-day (HERA, 2014). [Kl. score = 2]

Inhalation

Male and female rats were exposed by inhalation to 0, 0.2, 1.0, or 5.0 mg/m^3 sodium polyacrylate (MW 4,500) as an aerosol for 6 hours/day, 5 days/week for 13 weeks. Additional groups of animals were exposed for 13 weeks followed by a 91-day recovery period. There were no treatment-related effects on body weights, organ weights, feed and water consumption, clinical observations, and blood chemistry. In the histopathologic examination, the lungs of the mid- and high-dose animals showed signs of mild pulmonary irritation: increases in polymorphonuclear granulocytes or alveolar macrophages, pneumocyte hyperplasia, alveolar wall thickening and focal alveolitis. The lung effects were reversible and were not seen in the recovery group animals. The NOEC for systemic effects in this study was considered to be 5 mg/m^3, and the NOEC for localized irritation is 0.2 mg/m^3 (HERA, 2014). [Kl. score = 2]

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* studies on sodium polyacrylates are presented below in Table 1. All of the studies show that sodium polyacrylates are not mutagenic or genotoxic.

Table 1: In Vitro Genotoxicity Studies on Sodium Polyacrylates (HERA, 2014)

Mean MW	Test System	Results*	Klimisch Score	Reference
2,000	Bacterial reverse mutation	-	2	HERA (2014)
2,000	Mouse lymphoma	-	2	HERA (2014)
2,000	Unscheduled DNA synthesis	-	2	HERA (2014)
4,500	Bacterial reverse mutation	-	2	HERA (2014)
4,500	Mouse lymphoma	-	2	HERA (2014)
4,500	Unscheduled DNA synthesis	-	2	HERA (2014)
4,500	Cytogenetic (CHO cells)	-	2	HERA (2014)
4,500	Bacterial reverse mutation	-	2	HERA (2014)
4,500	Mammalian cell gene mutation	-	2	HERA (2014)
4,500	Unscheduled DNA synthesis	-	2	HERA (2014)

*+, positive; -, negative

In Vivo Studies

There was no increase in micronuclei in polychromatic erythrocytes from the bone marrow of mice given a single oral gavage dose of 13,850 mg/kg sodium polyacrylate with a MW of 2,000 (HERA, 2014).

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

No studies are available

I. Developmental Toxicity

Pregnant female rats were dosed by oral gavage with 0, 500, 1,000, or 3,000 mg/kg sodium polyacrylate (MW 4,500) on GD 6 to 15. At 3,000 mg/kg, the dams had soft or liquid stools during the treatment period. There was no maternal or developmental toxicity observed in this study. The NOAEL for maternal and developmental toxicity is 3,000 mg/kg-day (HERA, 2014). [Kl. score = 2]

Pregnant female rats were dosed by oral gavage with 0, 125, 375, or 1,125 mg/kg sodium polyacrylate (MW 90,000 as a 77.5% aq. solution) during GD 6 to 13. Some of the dams were sacrificed on GD 13 and the remaining on GD 19. One mid-dose dam and 6 high-dose dams died during the study; of these, three of the high-dose deaths were treatment-related and the remaining were considered the result of gavage errors. There was a transient decrease in feed consumption in the high-dose dams during GD 7-9, but not other indications of maternal toxicity. There was no developmental toxicity. The NOAELs for maternal and developmental toxicity are 375 and 1,125 mg/kg-day (HERA, 2014). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

NICNAS has assessed sodium polyacrylates in an IMAP Tier 1 assessment and considers it "a chemical identified as low concern to human health by application of expert validated rules".[1]

The toxicological reference values developed for sodium polyacrylates follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A 4-week dietary study showed no systemic toxicity in rats given 2.5% sodium polyacrylate (MW 2,500) in their feed. The estimated dose is 1,136 mg/kg-day. Two pre-natal developmental toxicity studies showed no effects at the highest dose tested: 3,000 and 1,125 mg/kg-day for sodium polyacrylates with MW of 4,500 and 90,000, respectively. The NOAEL of 1,136 mg/kg-day from the 4-week dietary study will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10

[1] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-i-human-health-assessments#cas-A_9003-04-7

UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subacute to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 1,136 (10 x 10 x 1 x 10 x 1) = 1,136/1,000 = 1.0 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD:

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

No carcinogenicity studies have been conducted on sodium polyacrylates. Therefore, a cancer reference value was not derived.

VI. Human Health Hazard Assessment of Physico-Chemical Properties

Sodium polyacrylates do not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium polyacrylates are a low toxicity concern for aquatic organisms, terrestrial invertebrates, and plants.

B. Aquatic Toxicity

Acute Studies
Table 2 lists the results of acute aquatic toxicity studies on sodium polyacrylates.

Table 2: Acute Aquatic Toxicity Studies on Sodium Polyacrylates

Mean MW	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
1,000	*Brachydanio rerio*	96-hr LC_{50}	>200	1	HERA, 2014
1,000	*Salmo gairdneri*	96-hr LC_{50}	>1,000	1	HERA, 2014
1,200	*Leuciscus idus*	96-hr LC_{50}	>500	1	HERA, 2014
2,000	*Brachydanio rerio*	96-hr LC_{50}	>200	1	HERA, 2014
2,500	*Leuciscus idus*	96-hr LC_{50}	>500	1	HERA, 2014
4,500	*Lepomis macrochirus*	96-hr LC_{50}	>1,000	1	HERA, 2014
4,500	*Lepomis macrochirus*	96-hr LC_{50}	>1,000	1	HERA, 2014
8,000	*Leuciscus idus*	96-hr LC_{50}	>500	1	HERA, 2014
10,000	*Lepomis macrochirus*	96-hr LC_{50}	>1,000	1	HERA, 2014
15,000	*Leuciscus idus*	96-hr LC_{50}	>10,000	1	HERA, 2014
78,000	*Brachydanio rerio*	96-hr LC_{50}	>400	2	HERA, 2014
1,000	*Daphnia magna*	48-hr EC_{50}	>200	1	HERA, 2014
1,000	*Daphnia magna*	48-hr EC_{50}	>1,000	1	HERA, 2014
2,000	*Daphnia magna*	48-hr EC_{50}	>200	1	HERA, 2014
4,500	*Daphnia magna*	48-hr EC_{50}	>200	1	HERA, 2014
4,500	*Daphnia magna*	48-hr EC_{50}	>1,000	1	HERA, 2014
78,000	*Daphnia magna*	24-hr EC_{50}	276	2	HERA, 2014
8,000	*Selenastrum capricornutum*	72-hr EC_{50}	40	1	HERA, 2014
78,000	*Scenedesmus subspicatus*	96-hr EC_{50}	44	2	HERA, 2014

Chronic Studies

Table 3 lists the results of chronic aquatic toxicity studies on sodium polyacrylates.

Table 3: Chronic Aquatic Toxicity Studies on Sodium Polyacrylates (HERA, 2014)

Mean MW	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
4,500	*Pimephales promelas*	32-d NOEC	56	2	HERA, 2014
4,500	*Brachydanio rerio*	28-d NOEC	>450	1	HERA, 2014
78,000	*Brachydanio rerio*	14-d NOEC	>400	2	HERA, 2014
4,500	*Daphnia magna*	21-d NOEC	450	1	HERA, 2014
4,500	*Daphnia magna*	21-d NOEC	58	1	HERA, 2014
4,500	*Daphnia magna*	21-d NOEC	12	2	HERA, 2014
78,000	*Daphnia magna*	21-d NOEC	100	2	HERA, 2014
4,500	*Scenedesmus subspicatus*	96-hr NOEC	180	2	HERA, 2014

Mean MW	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
78,000	*Scenedesmus subspicatus*	96-hr NOEC	32.8	2	HERA, 2014

There is considerable variability in the chronic aquatic toxicity results for *Daphnia magna* for sodium polyacrylates with the same molecular weight of 4,500. This was discussed in HERA (2014) and was explained by the solubility of sodium polyacrylates in water. In distilled water, the solubility of sodium polyacrylates with the molecular weight of 4,500 is >400 mg/L; however, under test conditions water solubility will decrease due to the presence of Ca^{++} and Mg^{++} (as measured by water hardness). In a study by BASF (reviewed in HERA, 2014), the water solubility of sodium polyacrylate (MW 4,500) was determined with radiolabelled compounds in a test system with a calcium concentration of 70 mg/L, which corresponds to the mean water hardness to the media used in an OECD TG 202 test. Under these conditions, the water solubility of sodium polyacrylate was 1.3 mg/L after 24 hours. Thus, the variability of the chronic *Daphnia* studies may be due to differences in water hardness.

C. Toxicity to Sediment Organisms

The 96-hr EC_0 to *Chironomus riparius* (larvae) is >4,500 mg/kg sediment dry weight (HERA, 2014).

D. Terrestrial Toxicity

The results of terrestrial toxicity studies on sodium polyacrylate polymers are listed below.

Table 4: Terrestrial Toxicity Studies on Sodium Polyacrylates (HERA, 2014)

Mean MW	Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
4,500	*Eisenia foetida*	14-d EC_0	1,000	1	HERA, 2014
78,000	*Eisenia foetida andrei*	14-d EC_0	1,000	2	HERA, 2014
78,000	*Brassica rapa*	21-d NOEC	1,000	2	HERA, 2014
4,500	Nitrogen transformation*	28-d EC_{10}	>2,500	1	HERA, 2014
4,500	Carbon transformation*	28-d EC_{10}	>2,500	1	HERA, 2014

*Soil organisms

E. Calculation of PNEC

The PNEC calculations for sodium polyacrylates follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (>200 mg/L), invertebrates (>200 mg/L), and plants (40 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 12 mg/L for invertebrates. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 12 mg/L for invertebrates. The $PNEC_{water}$ is 1.2 mg/L.

PNEC sediment

Experimental results are available for one trophic level. There were no visual signs of toxicity to *Chironomus riparius* (larvae) at the highest concentration tested (>4,500 mg/kg sediment dry weight) (HERA) 2014). The EC_0 is considered to be above 4,500 mg/kg and an assessment factor cannot apply. Thus, the equilibrium partitioning method will be used to determine the $PNEC_{sed}$. The HERA (2014) risk assessment calculated a $PNEC_{sed}$ of 130 mg/kg sediment wet weight using the default of 0.05 as the weight fraction of organic carbon in sediment according to the EU Technical Guidance Document (TGD) (EU 2003).

PNEC soil

Experimental results are available for three trophic levels. An acute LC_{50} value is available for earthworms (1,000 mg/kg soil dry weight). A 21-day NOEC for *Brassica rapa* was reported to be 1,000 mg/kg soil dry weight. Results from two long-term studies are available for soil microorganisms, with the NOECs for nitrogen and carbon transformation being >2,500 mg/kg soil dry weight. On the basis that the data consists of short-term tests, as well as one long-term test from one trophic level, an assessment factor of 100 has been applied to the lowest reported long-term NOEC of >2,500 mg/kg soil dry weight. The $PNEC_{soil}$ is 25 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009, ECHA, 2008).

The sodium polyacrylates are not readily biodegradable; thus they meet the screening criteria for persistence.

The sodium polyacrylates are expected to have high molecular weights and are not expected to be bioavailable. Thus these polymers do not meet the criteria for bioaccumulation.

Chronic NOECs for fish, daphnia and algae are available for sodium polyacrylates, and the NOEC values are >0.1 mg/L. Thus sodium polyacrylates do not meet the screening criteria for toxicity.

The overall conclusion is that sodium polyacrylates are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Aquatic Acute Toxicity Category 3

B. Labelling

Warning

According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye irritation and causes skin irritation.

C. Pictograms



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water..

Inhalation
If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
Burning produces harmful and toxic fumes. Heat from fire may melt, decompose polymer, and generate flammable vapors. Combustion products may include: Carbon monoxide, carbon dioxide, and unburned hydrocarbons (smoke). Dust can accumulate static charges which can cause an incendiary electrical discharge. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source, is a potential dust explosion hazard.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Potential combustible dust hazard. Avoid generating dust. Creates dangerous slipping hazard on any hard smooth surface.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilt
Scoop up and remove.

D. Storage and Handling

General Handling

Avoid dust accumulation in enclosed space. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Electrostatic charge may build up during handling. Equipment, container and metal containers should be grounded and bonded.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Use adequate ventilation to avoid excessive dust accumulation. Store away from excessive heat and away from strong oxidizing agents. Take measures to prevent the build-up of electrostatic charge.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure limit for sodium polyacrylates.

Engineering Controls

Use in a well ventilated area. Avoid creating dust. Take precautionary measures against static charge.

Personal Protection Equipment

Respiratory Protection: Not normally needed. But if significant exposures are possible then the following respirator is recommended:SEPDust/mist respirator.

Hand Protection: Normal work gloves.

Skin Protection: Normal work coveralls.

Eye protection: Wear safety glasses or goggles to protect against exposure.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium polyacrylates are not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HERA (2014). Human & Environmental Risk Assessment (HERA) on ingredients of European household cleaning products. Polycarboxylates used in detergents (Part I): Polyacrylic acid homopolymers and their sodium salts (CAS 9003-04-7). (http://www.heraproject.com/files/HERA_P-AA_final_v3_23012014.pdf)

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol, Pharmacol. 25:1-5.

SODIUM SULPHATE

This dossier on sodium sulphate presents the most critical studies pertinent to the risk assessment of sulphate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained the OECD-SIDS documents on sodium sulphate (OECD, 2005a,b), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Disodium sulphate

CAS RN: 7757-82-6

Molecular formula: Na_2SO_4

Molecular weight: 142.04 g/mol

Synonyms: Sodium sulphate; disodium sulphate; sodium bisulphate; sulphuric acid, disodium salt

SMILES: [O-]S(=O)(=O)[O-].[Na+].[Na+]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Sulphate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystalline solid	2	ECHA
Melting Point	ca. 884°C (pressure not reported)	2	ECHA
Density	2700 kg/m^3 @ 20°C	2	ECHA
Partition Coefficient (Log K_{ow})	-4.38 (temperature not provided)	2	ECHA
Water Solubility	445.5 g/L @ 20°C	1	ECHA
Auto flammability	Not auto flammable	1	ECHA

III. ENVIRONMENTAL FATE SUMMARY

Sodium sulphate dissociates in aqueous media to sodium (Na^+) and sulphate (SO_4^{2-}) ions. Biodegradation is not applicable to inorganic compounds. Sodium sulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Sodium sulphate is not expected to adsorb to soil or sediment because of its dissociation properties and high water solubility.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium sulphate exhibits low acute toxicity by the oral and inhalation routes. It is not irritating to the skin and eyes; and it is not a skin sensitiser. In a reproductive and developmental toxicity screening study, there was no indication of any toxicity in rats given oral doses as high as 1,000 mg/kg/day. Sodium sulphate is not genotoxic.

B. Acute Toxicity

Oral

The oral LD_{50} in rats is > 2,000 mg/kg (ECHA) [KI score = 1].

Human data indicate a very low acute toxicity of sodium sulphate. High oral doses of sodium sulphate, from 300 mg/kg up to 20 grams for an adult, are well tolerated, except from (intentionally) causing severe diarrhea (OECD, 2005a,b).

Inhalation

The 4-hour inhalation LC_{50} for an aerosol of sodium sulphate is > 2.4 mg/L, which was the highest technically feasible aerosol concentration. The mass median aerodynamic diameters (MMAD) were 2.65 to 2.71 µm (ECHA) [KI score = 1].

Dermal

There is no data on acute dermal toxicity.

C. Irritation

Application of 0.5 g sodium sulphate (in PEG 400) to the skin of rabbits for 4 hours was not irritating (ECHA) [KI score = 1].

Instillation of 90 mg sodium sulphate to the eyes of rabbits was not irritating (ECHA) [KI score = 1].

D. Sensitisation

Sodium sulphate was not considered a skin sensitiser in a mouse local lymph node assay (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

In a reproductive and developmental toxicity screening (OECD 421) study, male and female Wistar rats were dosed by oral gavage with 0, 100, 300 or 1,000 mg/kg sodium sulphate for a total of 4 weeks for males and 7 weeks for females. There was no evidence of toxicity at any dose level. The NOAEL for systemic toxicity is 1,000 mg/kg/day, the highest dose tested.

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on sodium sulphate are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Sodium Sulphate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium and E. coli strains)	-	-	1	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberration (Chinese hamster lung fibroblasts)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available.

G. Carcinogenicity

No valid studies are available.

H. Reproductive/Developmental Toxicity

A reproductive and developmental toxicity screening (OECD 421) study has been conducted on sodium sulphate. Male and female Wistar rats were dosed by oral gavage with 0, 100, 300 or 1,000 mg/kg sodium sulphate. There were no deaths during the study and no clinical signs of reproductive or developmental toxicity at any dose level. Body weights, body weight gain and feed consumption were similar across all groups. The NOAEL for systemic, reproductive and developmental toxicity is 1,000 mg/kg/day, the highest dose tested (ECHA) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived. Sodium sulphate dissociates in water to sodium and sulphate ions.

The Australian drinking water guideline value for sodium is 180 mg/L based on aesthetics (ADWG, 2021).

The Australian drinking water guideline value for sulphate is 500 mg/L based on health. Concentrations of > 500 mg/L can have purgative effects. There is also an Australian drinking water guideline value for sulphate of 250 mg/L based on aesthetics; it is the taste threshold (ADWG, 2021).

I. Cancer

There are no valid carcinogenicity studies on sodium sulphate. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium sulphate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

J. A. Summary

Sodium sulphate is of low acute concern to aquatic life.

K. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on sodium sulphate.

Table 3: Acute Aquatic Toxicity Studies on Sodium Sulphate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	7,960	2	Mount et al. (1997)
Daphnia magna	48-hour EC_{50}	4,736*	2	Davies and Hall (2007)

* Standard test conditions: 100 mg $CaCO_3$/L and Ca:Mg ratio of 0.7.

Chronic Studies

The 7-day LOEC from a *Ceriodapnia dubia* reproduction study, in which the test media contained varying degrees of water hardness, was 1,329 mg/L. The NOEC was extrapolated to be approximately 1,109 mg/L (Soucek, 2007).

L. Sediment Toxicity

The lowest 96-hour LC_{50} value to *Hyalella azteca* in a series of studies involving different hardnesses of water was 757 mg/L (Soucek and Kennedy, 2005). In another study with *Hyalella azteca*, the lowest 96-hour LC_{50} value (in water with the lowest hardness) was 841

mg/L (Davies and Hall, 2007). The lowest 96-hour LC_{50} value to *Chironomus tentans* in a series of studies involving different hardnesses of water was 20,899 mg/L (Soucek and Kennedy, 2005).

M. Terrestrial Toxicity

No adequate studies were located.

N. Calculation of PNEC

The PNEC calculations for sodium sulphate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute E(L)C50 values are available for fish (7,960 mg/L) and *Daphnia* (4,736 mg/L). The NOEC from a chronic study on invertebrates was 1,109 mg/L. On the basis that the data consists of results from short-term studies from two trophic levels and a single long-term study, an assessment factor of 100 has been applied to the chronic NOEC value of 1,109 mg/L for invertebrates. The $PNEC_{water}$ is 11 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Sodium sulphate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on its properties, no adsorption of sodium sulphate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of sodium sulphate is dominated by its water solubility. Sorption of sodium sulphate should probably be regarded as a reversible situation, i.e., the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, sodium sulphate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium sulphate is an inorganic salt that dissociates completely to sodium and sulphate ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and sulphate ions are also ubiquitous and are present in most water, soil and sediment. For

the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium sulphate or its dissociated ions.

Sodium and sulphate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. Thus, sodium sulphate is not expected to bioaccumulate.

The NOEC from a chronic toxicity study with *Ceriodaphnoa rerio* is > 0.1 mg/L. The acute E(L)C_{50} values for fish and *Daphnia* are > 1 mg/L. Thus, sodium sulphate does not meet the criteria for toxicity.

Therefore, sodium sulphate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal words.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact

Wash with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Do not induce vomiting. Rinse mouth with water and then drink a small amount of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: sodium and sulfur oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop and remove.

D. Storage And Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational standard for sodium sulphate.

Engineering Controls

Use in a well-ventilated area.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium sulphate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Davies, T.D. and Hall, K.J. (2007). Importance of calcium in modifying the acute toxicity of sodium sulphate to hyalella Azteca and Daphnia magna. Environ. Toxicol. Chem. 26: 1243-1247.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., and Evans, J.M. (1997). Statistical models to predict the toxicity of major ions to Ceriodaphnia dubia, Daphnia magna and Pimephales promelas (Fathead minnows). Environ. Toxicol. Chem. 16: 2009-2019.

OECD. (2005a). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium sulphate (CAS No. 7757-82-6), UNEP Publications.

OECD. (2005b). IUCLID Data Set for Sodium sulphate (CAS No. 7757-82-6), UNEP Publications.

Soucek, D.J. (2007). Comparison of hardness and chloride regulated acute effects of sodium sulphate on two freshwater crustaceans. Environ. Toxicol. Chem. 26: 773-779.

Soucek, D.J., and Kennedy, A.J. (2005). Effects of hardness, chloride, and acclimation on the acute toxicity of sulphate to freshwater invertebrates. Environ. Toxicol. Chem. 24: 1204-1210.

SODIUM SULPHITE

This dossier on sodium sulphite presents the most critical studies pertinent to the risk assessment of sodium sulphite in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Disodium sulphite

CAS RN: 7757-83-7

Molecular formula: Na_2SO_3

Molecular weight: 126.04

Synonyms: Sodium sulphite, disodium sulphite, sodium bisulphite anhydrous, sodium sulfite

SMILES: [O-]S(=O)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Sulphite

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, crystalline solid	2	ECHA
Melting Point	911°C	2	ECHA
Boiling Point	No data	-	-
Density	2.63 g/cm^3 @ 20°C	2	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	307 g/L @ 25°C	2	ECHA
Auto flammability	Not applicable	-	-

Sodium sulphite readily dissociates in aqueous media to the sodium (Na^+) and sulphite (SO_3^{2-}) ions. At neutral pH, a mixture of 50% sulphite (SO_3^{2-}) and 50% bisulphite (HSO_3^{2-}) is present.

In surface waters, sulphite is oxidized to sulfate either catalytically by air oxygen or by microbial action. The presence of cations like iron, copper or manganese in the environment accelerates the oxidation rate significantly.

III. ENVIRONMENTAL FATE PROPERTIES

At environmental pHs, sodium sulphite dissociates in water to form sodium (Na^+) ions, sulphite (SO_2^{3-}) ions, and bisulphite ions (HSO_3^-). In acidic solutions, sulfur dioxide (SO_2) gas may be formed.

Sodium sulphite is not expected to bioaccumulate in the environment because of its dissociation to ionic species and a gas. Furthermore, sulphite will oxidize to sulfate, which is ubiquitous in the environment.

Sodium sulphite and its dissociated species are expected to have a low potential to adsorb to soil and sediment.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium sulphite has low acute toxicity by the oral, inhalation and dermal routes. It is not irritating to the skin or eyes; it is not a skin sensitizer. No systemic toxicity was seen in rats when given sodium metabisulphite (which dissociates to the sulphite ion) in their diet over a lifetime. There were, however, indications of stomach lesions as a result of localized irritation from the ingestion of sodium metabisulphite. Genetic toxicity studies were negative. Lifetime oral feeding studies on sodium metabisulphite in rats and mice showed no evidence of carcinogenicity. No reproductive or developmental toxicity was observed in any of the animal studies on sodium metabisulphite.

B. Pharmacokinetics and Metabolism

Sodium sulphite is rapidly absorbed from the gastro-intestinal tract. Sulfate is the main metabolite formed by the action of sulphite oxidase in many tissues. Tissue accumulation of sulphite-derived S is highest in stomach, skin and hair, intestine and kidney. Excretion is rapid, mainly in the urine (OECD, 2008).

C. Acute Toxicity

The oral LD_{50} of sodium sulphite in rats is approximately 2,610 mg/kg (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats by nose-only exposure is >5.5 mg/L. The mass median aerodynamic diameter (MMAD) was 3.0 μm, with 90.7% of the dust being respirable (ECHA) [Kl. score = 2].

The acute dermal LD_{50} in rats is >2,000 mg/kg (ECHA) [Kl. score = 1].

D. Irritation

Application of 0.5 g sodium sulphite to the skin of rabbits for 4 hours under semi-occlusive conditions was non-irritating. The 24, 48, and 72 hour erythema and edema scores were 0.00 at all time points (ECHA) [Kl. score = 2].

Instillation of 162 mg sodium sulphite (equivalent to 0.1 mL bulk volume) into the eyes of rabbits was not irritating. The mean of the 24, 48, and 72 hour scores were: 0.00 for corneal lesions; 0.00 for iridial lesions; 0.9 for conjunctival redness; and 0.5 for chemosis (ECHA) [Kl. score = 2].

E. Sensitization

Sodium sulphite was not considered to be a skin sensitizer in a mouse local lymph node assay (ECHA) [Kl. score = 1].

F. Repeated Dose Toxicity

Oral

There are no studies available on sodium sulphite.

Male and female Wistar rats were given in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulphite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of sulphite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulphite from the feed containing sodium metabisulphite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. Addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The general condition of the rats was good during the first 72 weeks in the F_0 generation, as well as the other two generations. After 72 weeks, there was a rapid increase in mortality in all groups. Survival in the treated groups were generally higher than the controls, except for the 2% F_1 males; no deaths occurred in the 2% F_2 females. A marginal reduction in body weight gain was observed in the 2% dose group (both sexes) in the F_1 and F_2 generations. Feed consumption was similar between treated and control groups. There were no changes in hematology and clinical chemistry parameters and urinalysis that were considered toxicologically significant. The $\geq$1% dietary groups had occult blood in their feces. Relative kidney weights were increased in the 2% F_2 females, but there were no pathological changes noted in the kidneys from this group. Hyperplastic changes in the fore- and glandular stomachs were noted in the $\geq$1% groups in all three generations. Some slight alterations were also noted in stomachs of the 0.5% F_2 rats. The NOAEL for systemic toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g. The histopathologic effects on the stomach and the occult blood in feces are considered to be the result of localized irritation (a site-of-contact effect) from the ingestion of sodium metabisulphite (Til et al., 1972; ECHA). [Kl. score = 2]

Inhalation

No studies are available.

Dermal
No studies are available.

G. Genotoxicity

In Vitro Studies

The in vitro genotoxicity studies conducted on sodium sulphite and sodium metasulphite are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Sodium Sulphite and Sodium Metabisulphite

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)*	-	-	1	ECHA

*+, positive; -, negative
**Sodium metasulphite

In Vivo Studies

Sodium sulphite was not negative in a rat dominant lethal mutation assay. Male rats were fed in their diet 0, 4.5, 15, or 45 mg/kg-day sodium sulphite (ECHA) [Kl. score = 2].

Male and female NMRI mice were given a single oral gavage dose of 0, 250, 500, or 1,000 mg/kg sodium sulphite. There were no increases in chromosomal aberrations in the bone marrow cells of treated rats compared to the those in the control animals (ECHA) [Kl. score = 1].

H. Carcinogenicity

Oral
There are no carcinogenicity studies available sodium sulphite.

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulphite for up to two years and over three generations. There was no increased incidence of tumors in the treated groups compared to the controls (Til et al., 1972). [Kl. score = 2]

Male and female ICR/JCL mice were given 0, 1 or 2% potassium metabisulphite in drinking water for 104 weeks. There were no increased incidences of tumors in the treated mice compared to controls (Taneka et al., 1994; ECHA) [Kl. score = 2].

I. Reproductive Toxicity

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulphite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of sulphite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulphite from the feed containing sodium metabisulphite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. Addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The effects other than reproductive and developmental toxicity are discussed above in the Repeated Dose Toxicity section. There were no treatment-related effects on female fertility, the number of young per litter, or birth weight or mortality of the offspring. The number of F_{2a} pups was significantly reduced in the $\geq$0.5% groups during the first breeding cycle, but there was no dose-response and the reduction did not occur during the second breeding cycle. Slight growth retardation was observed in the F_1 and F_2 generation rats both before and after weaning. The NOAEL for reproductive toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g (Til et al., 1972; ECHA). [Kl. score = 2]

Male and female rats were given sodium metabisulphite in their drinking water for up to 2.5 years and in three successive generations. The doses were 375 and 750 ppm as sulfur dioxide (SO_2). There was no evidence of systemic toxicity in either dose group. The number of offspring of either the F_1 and F_2 generation and the proportion surviving to the end of lactation were similar between treated and control groups. The NOAEL for reproductive toxicity is 750 ppm (as SO_2) in drinking water. Assuming an average rat body weight of 400 g and a daily water intake of 28 mL, 750 ppm (as SO_2) corresponds to 53 mg/kg-day sodium metabisulphite (Lockett and Natoff, 1960; ECHA). [Kl. score = 2]

J. Developmental Toxicity

Pregnant female Wistar rats were fed in the diet 0, 0.32, 0.63, 1.25, 2.5, or 5% sodium sulphite ($Na_2SO_3 \bullet 7H_2O$) during GD 8 to 20. Maternal body weight gain and feed consumption were reduced in the 5% dose group. There was some evidence of reduced body weight gain in all treated groups, but there was no dose-response relationship and these effects were not observed in the live birth component of the study. The live birth component showed no treatment-related changes in the pups at three weeks after birth. There was no evidence of teratogenicity. The NOAELs for maternal and developmental toxicity are 2.5% and 5% in the diet, respectively. The calculated daily doses are approximately 850 and 1,450 mg/kg-day, respectively (ECHA). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for sodium sulphite follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

There was no evidence of systemic toxicity in a two-year rat dietary study on sodium metabisulphite (Til et al., 1972), the highest dose being 2% sodium in feed (estimated to be 955 mg/kg-day). The NOAEL of 955 mg/kg-day from this study will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Conversion of dose from sodium metabisulphite to sodium sulphite:

Molecular weight of sodium metabisulphite: 190.1 g/mol
Molecular weight of sodium sulphite: 126.04 g/mol

NOAEL = 955 x 126.04/190.1 = 633 mg/kg-day (as sodium sulphite)

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 633/(10 x 10 x 1 x 1 x 1) = 633/100 = 6 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (6.3 x 70 x 0.1)/2 = 22 mg/L

B. Cancer

No carcinogenic effects were reported for sodium metabisulphite in rat and mouse chronic studies. Thus, a cancer reference value for sodium sulphite was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium sulphite does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium sulphite is of moderate acute toxicity, but low chronic toxicity, concern to aquatic life.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on sodium sulphite and sodium disulphite.

Table 3: Acute Aquatic Toxicity Studies on Sodium Sulphite and Sodium Disulphite

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Golden orfe	96-hr LC_{50}	316	2	ECHA
Daphnia magna	48-hr EC_{50}	89* (59)	2	ECHA
Desmodesmus subspicatus	72-hr EC_{50}	43.8* (29)	2	ECHA

*Test substance: sodium disulphite

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies conducted on sodium sulphite and sodium disulphite.

Table 4: Chronic Aquatic Toxicity Studies on Sodium Sulphite and Sodium Disulphite

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Zebrafish	34-d NOEC	>316	1	ECHA
Daphnia magna	21-d NOEC	>10* (6.6)	1	ECHA
Desmodesmus subspicatus	EC_{10}	33.3* (22)	2	ECHA

*Test substance: sodium disulphite; adjusted concentration for sodium sulphite in parentheses.

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for sodium sulphite follow the methodology discussed in DEWHA (2009).

The PNEC calculations for sodium metabisulphite follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (316 mg/L), *Daphnia* (59 mg/L), and algae (29 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC or EC_{10} being 6.6 mg/L for invertebrates. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 6.6 mg/L for invertebrates. The $PNEC_{water}$ is 0.7 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. Sodium sulphite dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphite. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on the its properties, no adsorption of sodium sulphite to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. Sodium sulphite dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphite. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on the its properties, no adsorption of sodium sulphite to soil is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium sulphite is an inorganic compound that dissociates completely to sodium ions, sulphite and bisulphite ions, and sulfur dioxide in aqueous solutions. Biodegradation is not applicable to these compounds. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium sulphite or its dissociated compounds.

Sodium sulphite is an inorganic compound that dissociates completely in water to ionic compounds and a gas. Thus, it is not expected to bioaccumulate.

Chronic aquatic toxicity data on sodium sulphite and sodium disulfate; the NOECs are >0.1 mg/L. Thus, sodium sulphite is not expected to meet the criteria for toxicity.

Therefore, sodium sulphite is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Aquatic Acute Toxicity Category 3

B. Labelling

No signal word.

C. Pictogram

None

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards
When contacted by water, sodium metabisulphite releases sulfur dioxide (SO_2), a poisonous gas. In the case of fire, the following may be liberated: Sulfur oxides and sulfur dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas. When contacted by water, sodium metabisulphite releases sulfur dioxide (SO_2), a poisonous gas.

Steps to be Taken if Material is Released or Spilled
Scoop up and remove.

D. Storage And Handling

General Handling
When sodium metabisulphite gets wet or moist, it liberates sulfur dioxide (SO_2), a poisonous gas. Use proper protective equipment and exposure controls to prevent exposure to this toxic gas.

Other Handling Precautions
Avoid eye and skin contact. Avoid creating or inhaling dust. Keep away from acids and oxidizing agents.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

A workplace exposure standard is not available in Australia for sodium sulphite. However, the workplace exposure standards for sodium metabisulphite (disulphite) and sodium bisulphite in Australia is 5 mg/m^3 as an 8-hr TWA.

Engineering Controls
None

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Chemical resistant protective gloves.

Skin *Protection*:
Body protection must be chosen depending on activity and possible exposure.

Eye protection*:*
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium sulphite is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2008). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium Sulphite (CAS No. 7757-83-7). Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=AF456240-42B5-4118-8E97-4FE480D85FB9.

Tanaka, T., Fujii, M., Mori, H., and Hirono, I. (1979) Carcinogenicity test of potassium metabisulphite in mice. Ecotoxicol. Environ. Safety 3: 451-453.

Til, H.P., Feron, V.P., de Groot, A.P. (1972). The toxicity of sulphite. I. Long-term feeding and multigeneration studies in rats. Fd. Cosmet. Toxicol. 10: 291-310.

SODIUM THIOSULFATE

This dossier on sodium thiosulfate presents the most critical studies pertinent to the risk assessment of sodium thiosulfate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Disodium sulfanidesulfonate

CAS RN: 7772-98-7

Molecular formula: $Na_2S_2O_3$

Molecular weight: 158.1

Synonyms: Sodium thiosulfate; disodium sulfanidesulfonate; sodium thiosulphate; thiosulfuric acid, disodium salt; disodium sulfurothioate

SMILES: [O-]S(=O)(=S)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Thiosulfate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless crystalline solid	2	ECHA
Melting point	<500°C (decomposition occurs)	1	ECHA
Density	1.69 g/cm^3 @ 20°C	2	ECHA
Water solubility	764 g/L @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Sodium thiosulfate dissociates in aqueous media to sodium (Na^+) and thiosulfate ($S_2O_3^{2-}$) ions. The thiosulfate anion is stable in neutral or alkaline media, but not in acidic media (EPA, 2007). In aqueous media, thiosulfate irreversibly disproportionates to sulfide and sulfate (EPA, 2007).

Biodegradation is not applicable to inorganic compounds. Sodium thiosulfate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Sodium

thiosulfate is not expected to absorb to soil or sediment because of its dissociation properties and high water solubility.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance is of low acute and chronic toxicity via oral dosing. It is not an irritant nor does it illicit skin sensitization effects. The substance does not exhibit genotoxicity, mutagenicity or reproductive/developmental toxicity .

B. Acute Toxicity

No acute toxicity studies are available for sodium thiosulfate.

The oral LD_{50} of potassium thiosulfate in rats is >2,500 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} of calcium thiosulfate in rats is >2,000 mg/kg (ECHA) [Kl. score = 1].

The inhalation 4-hr LC_{50} of potassium thiosulfate in rats is >2,500 mg/kg (ECHA) [Kl. score = 2].

The dermal LD_{50} of potassium thiosulfate in rabbits is >2.6 mg/L aerosol. The mass median aerodynamic diameter was 2.1 μm (ECHA) [Kl. score = 2].

C. Irritation

No reliable skin irritation studies are available for sodium thiosulfate or other thiosulfate salts.

Instillation of 0.1 mL ammonium thiosulfate into the eyes of rabbits was not irritating. The mean of the 24, 48, and 72 hour scores were: 0.00 for corneal opacity; 0.00 for iridial lesions; 0.56 for conjunctival redness; and 0.11 for chemosis (ECHA) [Kl. score = 2].

D. Sensitization

Ammonium thiosulfate was not considered to be a skin sensitizer in a mouse local lymph node assay (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

<u>Oral</u>
No studies are available on the thiosulfate salts. Under acidic conditions, thiosulfates will disproportionate in aqueous mediate to form polythionic acids and bisulfite (HSO_3^-) ions plus sulfur dioxide gas (SO_2) (ECHA). A 2-year three-generation rat study on sodium metabisulfite will be used to read-across to sodium thiosulfate because sodium metabisulfite dissociates in water to form sodium (Na^+) ions, disulfite ($S_2O_5^{2-}$) ions, and sulfur dioxide (SO_2). The disulfite ions can form bisulfite (HSO_3^-) and sulfite ions (SO_2^{3-}) in varying proportions dependent on the pH of the solution (OECD, 2001).

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of the sulfite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulfite from the feed containing sodium metabisulfite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. The addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The general condition of the rats was good during the first 72 weeks of the F_0 generation, as well as the other two generations. After 72 weeks, there was a rapid increase in mortality in all groups. Survival in the treated groups was higher than the controls, except for the 2% F_1 males; no deaths occurred in the 2% F_2 females. A marginal reduction in body weight gain was observed in the 2% dose group (both sexes) in the F_1 and F_2 generations. Feed consumption was similar was between treated and control groups. There were no changes in haematology and clinical chemistry parameters and urinalysis that were considered toxicologically significant. The $\geq$1% dietary groups had occult blood in their feces. Relative kidney weights were increased in the 2% F_2 females, but there were no pathological changes noted in the kidneys from this group. Hyperplastic changes in the fore- and glandular stomachs were noted in the $\geq$1% groups in all three generations. Some slight alterations were also noted in stomachs of the 0.5% F_2 rats. The NOAEL for systemic toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g. The histopathologic effects on the stomach and the occult blood in feces are considered to be the result of localised irritation (a site-of-contact effect) from the ingestion of sodium metabisulfite (Til et al., 1972; ECHA). [Kl. score = 2]

Inhalation
No studies are available.

Dermal
No studies are available.

F. Genotoxicity

In Vitro Studies

No studies are available on sodium thiosulfate. The in vitro genotoxicity studies on ammonium thiosulfate are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Ammonium Thiosulfate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Mammalian cell gene mutation	-	-	1	ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
(mouse lymphoma L5178Y cells)				
Chromosomal aberration (Chinese hamster ovary cells)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available.

G. Carcinogenicity

Oral

No studies are available on the thiosulfate salts. Under acidic conditions, thiosulfates will disproportionate in aqueous mediate to form polythionic acids and bisulfite (HSO_3^-) ions plus sulfur dioxide gas (SO_2) (ECHA). A 2-year three-generation rat study on sodium metabisulfite will be used to read-across to sodium thiosulfate because sodium metabisulfite dissociates in water to form sodium (Na^+) ions, disulfite ($S_2O_5^{2-}$) ions, and sulfur dioxide (SO_2). The disulfite ions can form bisulfite (HSO_3^-) and sulfite ions (SO_2^{3-}) in varying proportions dependent on the pH of the solution (OECD, 2001).

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. There was no increased incidence of tumours in the treated groups compared to the controls (Til et al., 1972). [Kl. score = 2]

Male and female ICR/JCL mice were given in their drinking water 0, 1, or 2% potassium metabisulfite for two years. There was no increased incidence of tumours in the treated groups compared to the controls (Tanaka et al., 1979). [Kl. score = 2]

H. Reproductive Toxicity

No studies are available on the thiosulfate salts. Under acidic conditions, thiosulfates will disproportionate in aqueous mediate to form polythionic acids and bisulfite (HSO_3^-) ions plus sulfur dioxide gas (SO_2) (ECHA). A 2-year three-generation rat study on sodium metabisulfite will be used to read-across to sodium thiosulfate because sodium metabisulfite dissociates in water to form sodium (Na^+) ions, disulfite ($S_2O_5^{2-}$) ions, and sulfur dioxide (SO_2). The disulfite ions can form bisulfite (HSO_3^-) and sulfite ions (SO_2^{3-}) in varying proportions dependent on the pH of the solution (OECD, 2001).

Male and female Wistar rats were fed in their diet 0, 0.125, 0.25, 0.5, 1.0, or 2.0% sodium metabisulfite for up to two years and over three generations. The diet was enriched with thiamine to prevent thiamine deficiency as a result of the sulfite-induced destruction of this vitamin. During storage up to the time of consumption, the losses of sulfite from the feed

containing sodium metabisulfite at levels of 0.125, 0.25, 0.5, 1.0, and 2.0% averaged 22, 14,12, 8, and 4.5%, respectively, while the decrease in thiamine was 2.7, 1.7, 8.3, 14.5, and 15.4%, respectively. The addition of thiamine to the diet prevented thiamine deficiency in rats at all dose levels based on measurements of thiamine levels in the urine and liver. The effects other than reproductive and developmental toxicity are discussed above in the Repeated Dose Toxicity section. There were no treatment-related effects on female fertility, the number of young per litter, or birth weight or mortality of the offspring. The number of F_{2a} pups was significantly reduced in the $\geq$0.5% groups during the first breeding cycle, but there was no dose-response, and the reduction did not occur during the second breeding cycle. Slight growth retardation was observed in the F_1 and F_2 generation rats both before and after weaning. The NOAEL for reproductive toxicity is 1.91% in the diet. This was estimated to be 955 mg/kg-day based on a rat body weight of 400 g and a daily feed intake of 20 g (Til et al., 1972; ECHA). [Kl. score = 2]

Male and female rats were given sodium metabisulfite in their drinking water for up to 2.5 years and three successive generations. The doses were 375 and 750 ppm as sulfur dioxide (SO_2). There was no evidence of systemic toxicity in either dose group. The number of offspring of either the F_1 and F_2 generation and the proportion surviving to the end of lactation were similar between treated and control groups. The NOAEL for reproductive toxicity is 750 ppm (as SO_2) in drinking water. Assuming an average rat body weight of 400 g and a daily water intake of 28 mL, 750 ppm (as SO_2) corresponds to 53 mg/kg-day sodium metabisulfite (Lockett and Natoff, 1960; ECHA). [Kl. score = 2]

I. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0, 4, 19, 86, or 400 mg/kg sodium thiosulfate on GD 6 to 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 400 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 5.5, 25.5, 118, or 555 mg/kg sodium thiosulfate on GD 6 to 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 555 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female Dutch-belted rabbits were dosed by oral gavage with 0, 5.8, 27, 125.4, or 580 mg/kg sodium thiosulfate on GD 6 to 18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 580 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

A. Non-Cancer

Oral

An oral reference dose and drinking water guidance value was not derived for sodium thiosulfate. NICNAS does not consider sodium thiosulfate to pose an unreasonable risk to the health of workers and public health on the basis of the Tier I IMAP assessment.[1]

The Australian drinking water guideline values for sodium and sulfate may apply to sodium thiosulfate.

B. Cancer

Sodium or potassium metasulfite were not carcinogenic to rodents in two-year dietary studies. Thus, a cancer reference value was not derived for sodium thiosulfate.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium thiosulfate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance does not appear to exhibit significant acute aquatic toxicity. No data are available for chronic toxicity studies.

B. Aquatic Toxicity

Acute Studies

No data are available on sodium thiosulfate. Table 3 lists the results of acute aquatic toxicity studies conducted on ammonium thiosulfate.

Table 3: Acute Aquatic Toxicity Studies on Ammonium Thiosulfate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Lepomis macrochirus	96-hr LC_{50}	510	1	ECHA
Salmo gairdneri	96-hr LC_{50}	770	1	ECHA
Daphnia magna	48-hr EC_{50}	230	1	ECHA

[1] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/human-health-assessments#cas-A_7772-98-7.

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pseudokirchneriella subcapitata	72-hr EC_{50}	>100	1	ECHA

Chronic Studies
No data are available.

C. Terrestrial Toxicity

No terrestrial toxicity data are available for this substance.

D. Calculation of PNEC

The PNEC calculations for sodium thiosulfate follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available on ammonium thiosulfate for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (510 mg/L), Daphnia (230 mg/L), and algae (100 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported $E(L)C_{50}$ value of 100 mg/L for algae. The $PNEC_{water}$ for ammonium thiosulfate is 1.0 mg/L. Conversion of this value to sodium thiosulfate using the molecular weights of ammonium thiosulfate (148.21 g/mol) and sodium thiosulfate (258.11 g/mol) results in a $PNEC_{water}$ value for sodium thiosulfate of 1.1 mg/L.

PNEC sediment
No experimental toxicity data on sediment organisms are available. Sodium thiosulfate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium thiosulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on the its properties, no adsorption of sodium thiosulfate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil
No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of sodium thiosulfate is dominated by its water solubility. Sorption of sodium thiosulfate should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium thiosulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on the its properties, sodium thiosulfate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium thiosulfate is an organic salt that dissociates completely to sodium, sulfide, and sulfate ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; these ionic species are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium thiosulfate or its dissociated ions.

Sodium thiosulfate dissociates to ionic species. The sulfide ion can be oxidized by bacteria to sulfate. The sodium and sulfate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. Thus, sodium thiosulfate is not expected to bioaccumulate.

There are no chronic toxicity studies on sodium thiosulfate. The acute $EC(L)_{50}$ values are >1 mg/L in fish, invertebrates and algae. Thus, sodium thiosulfate does not meet the screening criteria for toxicity.

The overall conclusion is that sodium thiosulfate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None

X. HANDLING AND SAFETY (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air.

Ingestion
Rinse mouth with water and then drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray or fog, carbon dioxide, dry powder.

Specific Exposure Hazards
Burning produces harmful and toxic fumes.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
No special precautions are necessary. Ensure adequate ventilation.

Environmental Precautions
Do not discharge into drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilt
For large amounts: dike spillage and pump off the product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions
Protect against fire and explosion: prevent electrostatic charge; sources of ignition should be kept well clear, and fire extinguishers should be kept handy.

Storage
Keep container tightly closed and dry. Protect against heat. Store below 25oC.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Occupational exposure standards for the low molecular weight PEGs have not been established.

Engineering Controls

Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment
Respiratory Protection: Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Body protection must be chosen depending on activity and possible exposure.Safety glasses with side-shields.

Other Precautions: Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for sodium thiosulfate.

Engineering Controls
Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment
Respiratory Protection: Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Body protection must be chosen depending on activity and possible exposure.Safety glasses with side-shields.

Other Precautions: Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium thiosulfate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lockett, M.F., and Natoff, I.L. (1960). A study of the toxicity of sulfite. 1. J. Pharm. Pharmacol. 12: 488-496.

OECD (2001). OECDS-SIDS

OECD (2001). OECDS-SIDS: Disodium disulphite (CAS No. 7657-4). UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/DISODIUM.pdf

Tanaka, T., Fujii, M., Mori, H., and Hirono, I. (1979) Carcinogenicity test of potassium metabisulfite in mice. Ecotoxicol. Environ. Safety 3: 451-453.

Til, H.P., Feron, V.P., de Groot, A.P. (1972). The toxicity of sulphite. I. Long-term feeding and multigeneration studies in rats. Fd. Cosmet. Toxicol. 10: 291-310.

U.S. EPA [EPA] (2007). Reregistration Elibility Decision (RED) for Ammonium Thiosulfate, Office of Prevention, Pesticides and Toxic Substances, EPA 738-R-07-001, December 20, 2007.

SORBITAN, MONO-9-OCTADECENOATE, (Z)

This dossier on sorbitan, mono-9-octadecenoate, (Z) presents the most critical studies pertinent to the risk assessment of sorbitan, mono-9-octadecenoate, (Z) in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): [(2*R*)-2-[(2*R*,3*R*,4*S*)-3,4-dihydroxyoxolan-2-yl]-2-hydroxyethyl] (*Z*)-octadec-9-enoate

CAS RN: 1338-43-8

Molecular formula: $C_{24}H_{44}O_6$

Molecular weight: 428

Synonyms: Sorbitan monooleate; sorbitan, mono-9-octadecenoate, (Z)

SMILES: CCCCCCCCC=CCCCCCCCC(=O)OCC(C1C(C(CO1)O)O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

No experimental information is available on sorbitan, mono-9-octadecenoate, (Z).

Table 1: Overview of the Physico-chemical Properties of Sorbitan Stearate (CAS No. 1338-41-6)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White-to-tan waxy solid	2	ECHA
Melting point	55°C >49 to <65°C	2 2	ECHA
Boiling point	No data	-	ECHA
Density	0.942 g/cm^3 @ 100°C	2	ECHA
Vapor pressure	0 Pa @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	5.19 (QSAR)	2	EPA, 2019

Property	Value	Klimisch score	Reference
	5.89 (QSAR)*		
Water solubility	0.012 mg/L @ 25°C (QSAR)	2	ECHA
Flash point	225°C	2	ECHA
Viscosity	51 mm^2/s @ 100°C	2	ECHA

*Sorbitan, mono-9-octadecenoate, (Z)

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Biodegradability is likely to vary depending on the specific molecular structure of the substance. It is predicted to have a relatively low Kow, log Koc, and BCF. There is some potential for bioaccumulation based on performed modelling, but metabolic processes are expected to mitigate significant bioaccumulation in the environment.

B. Biodegradation

Sorbitan mono-9-octadecenate, (Z) is inherently biodegradable.

Sorbitan, mono-9-octadecenoate, (Z) is not readily biodegradable. In an OECD 301 C test, degradation was 43% after 10 days and 62% after 28 days (HPVIS).

Sorbitan stearate is readily biodegradable. In an OECD 301 C test, degradation was 88% after 28 days (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for sorbitan, mono-9-octadecenoate, (Z). Using KOCWIN in EPISUITE™ (EPA, 2019), the estimated K_{oc} value from log K_{ow} is 1,599 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 2,423 L/kg.

D. Bioaccumulation

There are no bioaccumulation studies on sorbitan, mono-9-octadecenoate, (Z). Sorbitan, mono-9-octadecenoate, (Z) has an estimated log K_{ow} of 5.89 (EPA, 2019). However, sorbitan, mono-9-octadecenoate, (Z) is expected to be metabolized and excreted. The metabolic pathway involves enzymatic hydrolysis by esterases to D-glucitol and the respective fatty acid. The fatty acids are metabolized by the beta-oxidation pathway and D-glucitol will undergo metabolism by the fructose metabolic pathway in the liver (ECHA). Using the Arnot-Gobas method involving biotransformation in the QSAR model BCFBAF v3.01, the BCF values ranged from 36 to 92 L/kg, indicating a low potential for bioaccumulation (EPA, 2019).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance is not significantly acutely toxic. It is not irritating nor is it expected to be a sensitizing agent despite the lack of data for this endpoint. Oral repeat dose studies suggest a low order of toxicity. The substance does not appear to be genotoxic, carcinogenic, or reproductively/developmentally toxic.

B. Toxicokinetics/Metabolism

Metabolism of the sorbitan esters in animals has been reported to occur initially via enzymatic hydrolysis, leading to sorbitan and the corresponding natural fatty acids. Oral gavage studies in rats with radiolabelled sorbitan monostearate, which is structurally similar to sorbitan, mono-9-octadecenoate, (Z), have demonstrated that about 90% of the sorbitan monostearate dose was absorbed and hydrolyzed to stearic acid and sorbitan (Elder, 1985; Wick, 1953). The resulting sorbitan and fatty acid metabolites, in turn would be expected to be metabolized further (via fatty acid beta-oxidation or carbohydrate metabolic pathways) to either smaller and more polar water-soluble metabolites, which can be excreted in the urine or as carbon dioxide exhaled in the lungs.

C. Acute Toxicity

No studies are available on sorbitan, mono-9-octadecenoate, (Z).

The oral LD_{50} in rats for sorbitan monopalmitate is >15,900 mg/kg (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} value for sorbitan monolaurate is >5 mg/L. The mass median aerodynamic diameter (MMAD) was 4.6 and 4.7 mm for two exposure periods (ECHA) [Kl. score = 2].

No acute dermal toxicity studies are available.

D. Irritation

Application of 0.5 g sorbitan palmitate to the skin of rabbits for 24 hours under occlusive conditions was not irritating (ECHA) [Kl. score = 2].

No eye irritation studies are available.

E. Sensitization

No studies are available.

F. Repeated Dose Toxicity

<u>Oral</u>

Sorbitan stearate was tested in a combined repeated dose toxicity study with a reproductive/developmental screening (OECD 422) test. Male and female SD rats were dosed by oral gavage with 0, 40, 200, or 1,000 mg/kg sorbitan stearate. There were no systemic effects that were considered to be treatment-related. The NOAEL for systemic toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Inhalation
No studies are available.

Dermal
No studies are available.

G. Genotoxicity

In Vitro Studies

There are no *in vitro* genotoxicity studies on sorbitan mono-9-octadecenate, (Z). Table 2 shows the results of *in vitro* genotoxicity studies on sorbitan stearate and sorbitan laurate.

Table 2: *In vitro* Genotoxicity Studies on Sorbitan Stearate and Sorbitan Laurate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)**	-	-	2	ECHA
Chromosomal aberration (human lymphocytes)**	-	-	2	ECHA

*+, positive; -, negative
**Read-across from sorbitan laurate (CAS No. 1338-43-8).

In Vivo Studies

No studies are available.

H. Carcinogenicity

No studies are available on sorbitan mono-9-octadecenoate, (Z).

Male and female TO mice were given in their diet 0, 0.5, 2, or 4% sorbitan stearate for 80 weeks. The estimated daily intakes were 0, 650, 2,600, and 5,200 mg/kg. Body weights were similar across all groups throughout the study. There were no increases in tumor incidence that were considered to be treatment-related (ECHA) [Kl. score = 2].

I. Reproductive/Developmental Toxicity

No studies are available on sorbitan mono-9-octadecenoate, (Z).

Sorbitan stearate was tested in a combined repeated dose toxicity study with a reproductive/developmental screening (OECD 422) test. Male and female SD rats were dosed by oral gavage with 0, 40, 200, or 1,000 mg/kg sorbitan stearate. There were no systemic, reproductive, or developmental effects that were considered to be treatment-related. The NOAEL for reproductive and developmental toxicity is 1,000 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for sorbitan mono-9-octadecenoate, (Z) follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

There are no repeated dose toxicity studies on sorbitan mono-9-octadecenoate, (Z). Sorbitan monostearate, a structurally similar substance to sorbitan mono-9-octadecenoate, (Z) has been tested in an OECD 422 rat oral gavage study. The NOAEL for systemic, reproductive, and developmental toxicity is 1,000 mg/kg-day. The NOAEL of 1,000 mg/kg-day will be used to derive an oral RfD and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 1,000/(10 x 10 x 1 x 10 x 1) = 1,000/1,000 = 1.0 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.04 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

There are no carcinogenicity studies on sorbitan mono-9-octadecenoate, (Z). Sorbitan monostearate was not carcinogenic to mice. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sorbitan mono-9-octadecenoate, (Z) does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is not significantly acutely toxic to aquatic organisms and does not exhibit substantial chronic toxicity to this receptor group. No terrestrial toxicity data are available.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on sorbitan, mono-9-octadecenoate, (Z) or sorbitan stearate.

Table 3: Acute Aquatic Toxicity Studies on Sorbitan, Mono-9-octadecenoate, (Z) and Sorbitan Stearate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Salmo gairdneri	96-hr LL_{50}	>1,000 [WAF]	2	HPVIS
Oryzias latipes	96-hr LL_{50}	>1,000 [WAF]*	1	ECHA
Daphnia magna	48-hr EL_{50}	>1,000 [WAF]*	1	ECHA
Pseudokirchneriella subcapitata	72-hr EL_{50}	>1,000 [WAF]*	1	ECHA

*Studies conducted on sorbitan stearate (CAS No. 1338-41-6).

Chronic Studies

The 21-day NOELR (no-observed-effect-loading-rate) in a *Daphnia* reproduction test for sorbitan stearate (CAS No. 1338-41-6) is 16 mg/L WAFA (ECHA) [Kl. score = 2].

The 72-hr NOELR (no-observed-effect-loading-rate) to *Pseudokirschneriella subcapitata* for sorbitan stearate is 560 mg/L [WAF] (ECHA) [Kl. score = 1].

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for sorbitan, mono-9-octadecenoate, (Z) follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)L_{50}$ values are available for fish (>1,000 mg/L WAF), invertebrates (>1,000 mg/L WAF), and algae (>1,000 mg/L WAF). Results from chronic studies are available for invertebrates (16 mg/L WAF) and algae (560 mg/L WAF). On the basis that the data consists of short-term studies for three trophic levels and long-term results studies for two trophic levels, an assessment factor of 50 has been applied to the lowest reported NOELR of 16 mg/L for invertebrates. The $PNEC_{water}$ is 0.32 mg/L WAF.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 10.3 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (48.46/1500) \times 1000 \times 0.32$
$= 10.3$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 2,423 \times 0.02$
$= 48.46$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for sorbitan, mono-9-octadecenoate, (Z) based on the molecular connectivity index (MCI) is 2,423 L/kg (EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sorbitan, mono-9-octadecenoate, (Z) is not readily biodegradable; however, it is expected to be inherently biodegradable; thus, it does not meet the screening criteria for persistence.

The estimated BCF values (involving biotransformation) for sorbitan, mono-9-octadecenoate, (Z) ranged from 36 to 92 L/kg. Thus, it does not meet the criteria for bioaccumulation.

The lowest chronic NOELR for sorbitan stearate, the surrogate for sorbitan, mono-9-octadecenoate, (Z), is >0.1 mg/L. The acute E(L)L_{50} values are >1 mg/L. Thus, sorbitan, mono-9-octadecenoate, (Z) does not meet the screening criteria for toxicity.

The overall conclusion is that sorbitan, mono-9-octadecenoate, (Z) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

No classified.

B. Labelling

No signal word.

C. Pictogram

None

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact
Wash thoroughly with soap and water.

Inhalation
If inhaled, remove from area to fresh air.

Ingestion

Rinse mouth with water and then drink plenty of water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray or fog, carbon dioxide, dry powder.

Specific Exposure Hazards
Burning produces harmful and toxic fumes.

Special Protective Equipment for Firefighters
Wear a self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions
No special precautions are necessary. Ensure adequate ventilation.

Environmental Precautions
Do not discharge into drains, sewers, or waterways.

Steps to be Taken if Material is Released or Spilt
For large amounts: dike spillage and pump off the product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Handle in accordance with good industrial hygiene and safety practice.

Other Handling Precautions
Protect against fire and explosion: prevent electrostatic charge; sources of ignition should be kept well clear, and fire extinguishers should be kept handy.

Storage
Keep container tightly closed and dry. Protect against heat. Store below 25oC..

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for sorbitan, mono-9-octadecenoate, (Z).

Engineering Controls
Provide local exhaust ventilation to control vapours and mists.

Personal Protection Equipment

Respiratory Protection:
Respiratory protection in case of vapours/aerosol release. Wear a certified organic vapour/particulate respirator.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Body protection must be chosen depending on activity and possible exposure.

Other Precautions:
Wash hands, forearms, and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sorbitan, mono-9-octadecenoate, (Z) is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances.

Elder, R.L. (1985). Final report on the safety assessment of sorbitan stearate, sorbitan laurate, sorbitan sesquioleate, sorbitan oleate, sorbitan tristearate, sorbitan palmitate, and sorbitan trioleate, J. Amer. Coll. Toxicol. 4(3): 65-121.

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HPVIS. U.S. EPA High Production Volume (HPV) Information System: U.S. HPV Test Plan and Robust Summaries for Sorbitan Esters Category of the Aliphatic Esters Chemicals, November 26, 2003. Available at: https://ofmpub.epa.gov/oppthpv/Public_Search.PublicDetails.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2019). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Wick, A.N., and Joseph, L. (1953). The metabolism of sorbitan monostearate. Food Res. 18: 79

SORBITAN MONOOLEATE POLYOXYETHYLENE DERIVATIVE

This dossier on sorbitan monooleate polyoxyethylene derivative presents the most critical studies pertinent to the risk assessment of sorbitan monooleate polyoxyethylene derivative in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA), and the European Food and Safety Authority (EFSA, 2015). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name: Sorbitan monooleate polyoxyethylene derivative

CAS RN: 9005-65-6

Molecular formula: C32H60O10(representative as per PubChem)

Molecular weight: 604.8 g/mol (representative per PubChem)

Synonyms: See below.

SMILES: CCCCCCCCC=CCCCCCCCC(=O)OCCOCC(C1C(C(CO1)OCCO)OCCO)OCCO (representative per PubChem)The composition of sorbitan monooleate polyoxyethylene derivative (CAS No. 9005-65-6) is unknown. The CAS No. 9005-65-6 is a generically CAS No. that can include at least the following UVCB substance groups (CIR, 2015):

1. An ethoxylated sorbitan ester of oleic acid with an average of 3 moles of ethylene oxide (e.g., PEG-3-sorbitan oleate).

2. A mixture of oleate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 5 moles of ethylene oxide (e.g., Polysorbate 81).

3. An ethoxylated sorbitan ester of oleic acid with an average of 6 moles of ethylene oxide (e.g., PEG-6 sorbitan oleate).

4. An ethoxylated sorbitan ester of oleic acid with an average of 20 moles of ethylene oxide (e.g., PEG-20 sorbitan oleate).

5. A mixture of oleate esters of sorbitol and sorbitol anhydrides, consisting predominantly of the monoester, condensed with approximately 20 moles of ethylene oxide (e.g., Polysorbate 80).

<u>This dossier includes information from the following substances:</u>

Sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-65-6]

Polysorbate 80 (CAS No. 9005-65-6)

Sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sorbitan Monooleate, Ethoxylated (1 – 6.5 Moles Ethoxylated) [CAS No. 9005-65-6]*

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid	2	ECHA
Melting point	-32.7°C -33.9°C	2 2	ECHA
Boiling point	No data	-	ECHA
Density	1.03 g/cm^3 @ 25°C	2	ECHA
Vapor pressure	0 Pa @ 20°C (QSAR)	2	ECHA
Partition coefficient (log K_{ow})	4.51 to 5.06 (QSAR)**	2	ECHA
Water solubility	35 to 100 mg/L @ 20°C***	1	ECHA
Flash Point	256°C	4	ECHA

*Data located in REACH database for dehydrated sorbitol, C18 (unsaturated) fatty acid esters, ethoxylated (EC No. 701-203-3).
**QSAR (KOWWIN v1.68): sorbitan monooleate, ethoxylated 5EO and sorbitan monooleate, ethoxylated 3EO, respectively.
***Sorbitan monooleate, ethoxylated 3EO: ~100 mg/L; sorbitan monooleate, ethoxylated 5EO: ~35 mg/L.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is readily biodegradable, is unlikely to sorb to sediments, and exhibits a low potential to bioconcentration and bioaccumulate.

B. Biodegradation

In an ISO Standard 14593 ready biodegradation test, degradation of Tween 81 (CAS No. 9005-65-6) was 61% after 28 days, indicating ready biodegradability (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for sorbitan monooleate polyoxyethylene derivative. Using KOCWIN v2.00, the estimated K_{oc} values for the main components in sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-65-6] based on the molecular connectivity index (MCI) ranged from 794 to 1,259 L/kg (ECHA).

The molecular structure indicates a potential of surface-active properties, which are not taken into account by the QSAR model calculations. The adsorption of non-ionic surfactants to soil is generally high (ECHA).

D. Bioaccumulation

There are no experimental bioaccumulation studies on sorbitan monooleate polyoxyethylene derivative. The bioaccumulation potential was estimated for sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-65-6] using BCFBAF v3.01 (Arnot-Gobas method, including biotransformation). The calculated BCF values were 12.6 to 14.6 L/kg. When biotransformation was excluded, the BCF values were 18.6 to 42.8 L/kg (ECHA). Thus, sorbitan monooleate polyoxyethylene derivative has a low potential for bioaccumulation.

IV. HUMAN HEALTH HAZARD ASSESSMENT

The information in this section is from studies conducted on the Polysorbates.

Polysorbate 80 is composed of a sorbitan ring with ethylene oxide polymers attached at three different hydroxyl positions. While the number of repeat ethylene oxide subunits varies at each position, their total number equals 20 and is constant for each polysorbate. The major fatty acid side chains of Polysorbate 80 is oleic acid. The commercial polysorbates are complex mixtures, *i.e.*, UVCB (Unknown or Variable Composition, Complex Reaction Products and Biological Materials) substances. The composition data reported in Kerwin *et al.* (2008) shows that oleic acid ester of Polysorbate 80 is $\geq$58% of the total number of fatty acid species; the remaining fatty acids are a mixture of both saturated and unsaturated fatty acids. The average molecular weight of Polysorbate 80 is 1,310 g/mol (Kerwin et al., 2008).

A. Summary

The acute toxicity of Polysorbate 80 is low by the oral and dermal routes. It is non-irritating to the skin and eyes, and it is not a dermal sensitizer. Polysorbate 80 is poorly absorbed from the gastrointestinal tract. Dietary studies conducted for up to two years with Polysorbate 80 indicate that it is essentially non-toxic to rats and mice. Polysorbate 20 is not genotoxic. A similar substance to Polysorbate 20 (Polysorbate 80) was not carcinogenic to mice when given in the diet; nor was it carcinogenic to female rats. Male rats showed a marginal increase in the number of benign adrenal medulla pheochromocytomas in the high-dose male rats. Adrenal medulla hyperplasia, a lesion considered to be the precursor to pheochromocytoma, was increased in the low-dose, but not high-dose, male rats. The increased adrenal medulla pheochromocytomas in the Polysorbate 80-treated male rats does not have relevance to

humans. This conclusion is based on the lack of genotoxicity of Polysorbate 80, the equivocal finding in the NTP study, and that pheochromocytomas have been associated with poorly metabolized food additives (*i.e.*, polyols such as sorbitol, xylitol, lactitol; lactose) given to animals at high doses and have been regarded as of no significance to humans. Polysorbates have not shown any indication of reproductive or developmental toxicity when tested in rats.

B. Toxicokinetics/Metabolism

Pharmacokinetic and metabolism studies are available for Polysorbate 20 and 80. These polysorbates have similar absorption, distribution, metabolic fate, and elimination, which would be expected given that they only differ in their fatty acid side-chain.

Following the oral administration of polysorbates, the ester link of the polysorbate molecule is hydrolyzed in the gastrointestinal tract by pancreatic lipase; the fatty acid moiety that is released is absorbed and metabolized by the same pathways that exist for long-chain fatty acids from dietary sources. The remaining polyoxyethylene sorbitan moiety is not well absorbed from the gastrointestinal tract and is excreted in the feces. The polyoxyethylene sorbitan moiety that is absorbed is not metabolized and is excreted in the urine (CIR, 1984).

Polysorbate 20 with [^{14}C]-labelled lauric acid was fed to rats. Twenty-hours later, 80% of the lauric acid was oxidized and expired as CO_2; 12% was in the carcass; 4% was not absorbed from the gastrointestinal tract; 2.5% was excreted in the urine; and 1.2% was in the liver (Nelson *et al.*, 1966).

In a study with the [^{14}C]-label in the polyoxyethylene portion of Polysorbate 20, 82-90% of the radioactivity was excreted in the feces and 8-11% in the urine, but little to no radioactivity was found in the liver, carcass, or expired CO_2 (Nelson *et al.*, 1966). When the sorbitol moiety of Polysorbate 80 was labeled, 91% of the radioactivity was recovered in the feces, 2.1% in the urine, 1.6% in the carcass, and none in expired CO_2, liver, kidney, spleen, adrenals, brain, gonads, or fat (Treon et al., 1967).

A similar pattern of polysorbate metabolism occurs in humans as in rats following oral administration (Culver *et al.*, 1951). In four subjects fed 4.5 g of unlabeled Polysorbate 80 per day (study duration not stated), 90-97% of the polyoxyethylene fraction was excreted in the feces, and 2.3-3.1% was excreted in the urine. The analytical method measured the oxyethylene value of Polysorbate 80 and could not distinguish between the free polyoxyethylene moiety and the unhydrolyzed parent ester. Since no fatty acids containing the polyoxyethylene moiety were detected in the urine, it was concluded that it was polyoxyethylene sorbitan excreted in the urine.

The Polysorbates are rapidly hydrolyzed by blood esterases following intravenous administration. In a study using mice, plasma concentrations of Polysorbate 80 rapidly declined to about 66% of the initial concentration by 15 minutes after post-bolus intravenous injection, with a plasma concentration of <0.05% (van Tellingen *et al.*, 1999). The released fatty acids are metabolized similar to other fatty acids in the blood, and the remaining polyoxyethylene moiety is not metabolized, but is excreted primarily in the urine (Nelson *et al.*, 1966). A small percentage is found in the feces, indicating biliary excretion (Nelson *et al.*, 1966; Treon et al., 1967).

C. Acute Toxicity

The oral LD_{50} values for Polysorbate 20 in rats are >36,700 mg/kg (ECHA) [Kl. score = 4]; >33,800 mg/kg (ECHA) [Kl. score = 4]; and >30 mL/kg (ECHA) [Kl. score = 4]. The oral LD_{50} value for mice is >30 mL/kg (ECHA) [Kl. score = 4].

No acute inhalation studies are available for the Polysorbates.

There are no acute dermal toxicity studies on Polysorbate 20. The dermal LD_{50} value in rats for Polysorbate 60 (polyoxyethylene sorbitan monostearate) is >2000 mg/kg (ECHA) [Kl. score = 4].

D. Irritation

Application of 0.5 mL Polysorbate 20 to the skin of rabbits for 4 hours under semi-occlusive conditions was not irritating (ECHA) [Kl. score = 1]. The mean of the 24-, 48-, and 72-hour scores were 0.89 for erythema and 0.00 for edema (ECHA) [Kl. score = 1].

Instillation of 0.1 mL Polysorbate 20 into the eyes of rabbits was not irritating. The mean of the 24-, 48-, and 72-hour scores were: 0.00 for corneal opacity; 0.00 for iridial lesions; and 0.00 for conjunctival redness (ECHA) [Kl. score = 2].

E. Sensitization

Polysorbate 20 was not considered a skin sensitizer when tested in a guinea pig maximization test (ECHA) [Kl. score = 1].

F. Repeated Dose Toxicity

The polysorbates have been well-studied in multiple species, including rats, mice, hamsters, monkeys and dogs. A complete review of all the studies can be found in JECFA (1974) and EFSA (2015). Two of the more reliable polysorbate studies were conducted on polyoxyethylene sorbitan monostearate or Polysorbate 60 (CAS No. 9005-67-8).

There does not appear to be any toxicological differences between the polysorbates. No target organs were identified in these studies, and diarrhea is the primary non-neoplastic effect at concentrations of $\geq$5% in feed. The diarrhea is related to the composition of the diet. Polysorbates in diets without dietary fiber resulted in exfoliated or damaged brush border membrane of the small intestinal cells, inducing diarrhea and reduced body weight (Kimura *et al.*, 1982).

Oral

Male and female Sprague-Dawley rats were given in their feed 0, 1, 2, or 5% Polysorbate 60 for 13 weeks. Effects were noted only in the 5% dietary group and consisted of diarrhea, increased water consumption, enlarged cecum, and slightly decreased hemoglobin. The NOAEL for this study is 2% in the diet, which corresponds to 1,355 and 1,565 mg/kg-day for males and females, respectively (BIBRA, 1981; EFSA, 2015) [Kl. score = 2].

Male and female Osborne-Mendel rats were given in their feed 0, 2, 5, 10, or 25% Polysorbate 60 or 24 months. There was no treatment-related mortality or in feed consumption. In the 25% dietary group, there was severe diarrhea and reduced body weight gain the males. Liver weights were increased with no corresponding histopathologic changes. The cecum was also enlarged, but the histopathologic examination showed no treatment-related changes. The only changes seen in the 10% and 5% dietary groups were moderate and slight diarrhea, respectively. The NOAEL for this study is 2% in the diet, which corresponds to 1,000 mg/kg-day (Fitzburgh et al., 1959; EFSA, 2015) [Kl. score = 2].

Male and female F344/N rats were given in their feed 0, 3,100, 6,200, 12,500, 25,000, or 50,000 ppm Polysorbate 80 for 13 weeks. There were no treatment-related effects. The NOAEL for this study is 50,000 ppm in the diet, which corresponds to 4,500 mg/kg-day (NTP, 1992a) [Kl. score = 2].

Male and female B6C3F_1 mice were given in their feed 0, 3,100, 6,200, 12,500, 25,000, or 50,000 ppm Polysorbate 80 for 13 weeks. There were no treatment-related effects. The NOAEL for this study is 50,000 ppm in the diet, which corresponds to 10,000 mg/kg-day (NTP, 1992a) [Kl. score = 2].

Male and female F344/N rats were given in their feed 0, 25,000 or 50,000 ppm Polysorbate 80 for two years. There was reduced survival in the male, but not female, rats; there were no other non-neoplastic treatment-related effects. The NOAEL for this study is 50,000 ppm in the diet, which corresponds to 2,500 mg/kg-day (NTP, 1992a) [Kl. score = 2].

Male and female B6C3F_1 mice were given in their feed 0, 25,000 or 50,000 ppm Polysorbate 80 for two years. The 50,000 ppm animals had forestomach squamous hyperplasia, and the 50,000 ppm females had forestomach ulcers. These effects were considered to be the localized effects of the test material and not due to systemic toxicity. The NOAEL for systemic toxicity in this study is 50,000 ppm in the diet, which corresponds to 3,700 mg/kg-day (NTP, 1992a) [Kl. score = 2].

Inhalation
No data are available.

Dermal
No data are available.

G. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on Polysorbate 80 are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Polysorbate 80

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium*)	-	-	2	EFSA, 2015
Chromosomal aberration (Chinese hamster fibroblasts)	-	-	2	EFSA, 2015

*+, positive; -, negative

In Vivo Studies

Male CBA mice were given a single oral gavage dose of 0 or 75 mg/kg Polysorbate 80. There was no significant increase in micronuclei in the bone marrow cells of the treated mice compared to controls (Jenssen and Ramel, 1980) [Kl. score = 2].

H. Carcinogenicity

The NTP conducted two-year dietary carcinogenicity studies on Polysorbate 80 in F344/N rats and $B6C3F_1$ mice. The dietary levels were 0, 25,000 or 50,000 ppm Polysorbate 80. The average daily intakes in rats were 0, 1,174, and 2,415 mg/kg-day for males; and 0, 1,344, and 2,745 mg/kg-day for females. There was no evidence of carcinogenic activity for Polysorbate 80 in female rats or in male and female mice at any dose level. In male rats, the incidence of benign or malignant adrenal medulla pheochromocytomas (combined) was significantly increased in the high-dose males (21/50, 19/50, and 29/50 for the 0, 25,000, and 50,000 ppm groups, respectively). The incidence of the high-dose group (58%) exceeded the upper historical control range of 48% for males from the current NTP 2-year dietary studies. But when NTP evaluated the historical control incidence in male F344/N rats based on a broader range of NTP studies than those included in the recent historical control data, the incidence of pheochromocytomas in untreated male rats was as high as 65% (Haseman *et al.*, 1990). The increased incidence of pheochromocytomas in the high-dose males was due to an increase in the number of benign pheochromocytomas occurring in a single gland. The incidence of hyperplasia of the adrenal medulla was increased in the low-dose male rats, but not in the high-dose male rats (11/50, 22/50, 12/50, respectively). The NTP concluded that the marginal increased incidence of pheochromocytomas in combination with the increased incidence of hyperplasia were considered to be an equivocal finding (NTP, 1992a) [Kl. score = 2].

A review of the NTP (1992a) data by the EU Scientific Committee on Foods (SCF, 1995) and a subsequent review by the European Food Safety Authority (EFSA, 2015) concluded that the increased adrenal medulla pheochromocytomas in the Polysorbate 80-treated male rats did not have relevance to humans. This conclusion was based on the lack of genotoxicity of Polysorbate 80, the equivocal finding in the NTP study, and that pheochromocytomas have been associated with poorly metabolized food additives (*i.e.*, polyols such as sorbitol, xylitol, lactitol; lactose) given to animals at high doses and have been regarded as of no significance to humans. In the long-term (mainly 2-year) studies on polyols and lactose, adrenal medullary hyperplasia and

pheochromocytomas occurred at dietary concentrations of ≥5% and usually at 10-20%, with no proliferative lesions and tumors seen at lower concentrations (reviewed in Lynch *et al.*, 1996). The pheochromocytomas in these studies were seen in rats, but not in mice and dogs, with male rats having a higher incidence than female rats. In their evaluation of the human significance of these tumors from polyols and lactose, Lynch *et al.* (1996) discuss the significant morphological, functional, and etiological differences between rats and humans with regards to the nature of proliferative lesions that occur in the adrenal medulla. They conclude that the rat is much more susceptible to induction of proliferative lesions of the adrenal medulla compared to humans. There are also mechanistic data on polyols and lactose that support a high-dose rat-specific mode-of-action for these adrenal medulla pheochromocytomas. Although there are no mechanistic studies on Polysorbate 80, the similarity in the toxicity profile of Polysorbate 80 with these poorly metabolized carbohydrates would suggest that the pheochromocytomas seen in the male rats in the NTP two-year carcinogenicity study also occurs by a high-dose rat-specific mode-of-action.

I. Reproductive Toxicity

In a three-generation reproductive toxicity study, male and female rats were given in their feed 0, 5, 10, or 20% (0, 2,500, 5,000, or 20,000 mg/kg-day) Polysorbate 80. Diarrhea was seen in the ≥10% parental animals. There was reduced postnatal survival in the pups in the 20% dietary group as well as reduced lactation and breeding efficiency. There were no other effects that were indicative of reproductive or developmental toxicity. The NOAEL for reproductive and developmental toxicity is 10% in the diet, which corresponds to 5,000 mg/kg-day (Oser and Oser, 1956a,b; Oser and Oser, 1957a,b) [Kl. score = 2].

J. Developmental Toxicity

Pregnant female SD rats were dosed by oral gavage with 0, 500, or 5,000 mg/kg Polysorbate 80 on GD 6-15. At 500 and 5,000 mg/kg, liver weights were slightly increased in the maternal dams, but the change was not enough to be considered adverse. There was no indication of developmental toxicity. The NOAEL for maternal toxicity is 5,000 mg/kg-day. The NOAEL for developmental toxicity is 5,000 mg/kg-day, the highest dose tested (NTP, 1992b; Price et al., 1994) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for Polysorbate 80 follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

A two-year carcinogenicity study was conducted in rats given 0, 25,000, or 50,000 ppm Polysorbate 80 in feed (NTP, 1992a). For non-cancer effects, there were no adverse findings at any dose level. In female rats, there were no carcinogenic effects; but in the male rats, there was a marginal increase in the number of benign adrenal medulla pheochromocytomas in the high-dose male rats. Adrenal medulla hyperplasia, a lesion considered to be the precursor to

pheochromocytoma, was increased in the low-dose, but not high-dose, male rats. The NOAEL for this study is 25,000 ppm for male rats, which corresponds to average daily intake of 1,174 mg/kg-day. The NOAEL of 1,174 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 1,174(10 x 10 x 1 x 1 x 1) = 1,174/100 = <u>12 mg/kg-day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (11.7 x 70 x 0.1)/2 = <u>41 mg/L</u>

B. Cancer

A two-year dietary carcinogenicity study on Polysorbate 80 showed a marginal increase in the number of benign adrenal medulla pheochromocytomas in the high-dose male rats. Adrenal medulla hyperplasia, a lesion considered to be the precursor to pheochromocytoma, was increased in the low-dose, but not high-dose, male rats. The increased adrenal medulla pheochromocytomas in the Polysorbate 80-treated male rats did not have relevance to humans. This conclusion was based on the lack of genotoxicity of Polysorbate 80, the equivocal finding in the NTP study, and that pheochromocytomas have been associated with poorly metabolized food additives (*i.e.*, polyols such as sorbitol, xylitol, lactitol; lactose) given to animals at high doses and have been regarded as of no significance to humans. A cancer reference value for Polysorbate 80 was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Polysorbate 80 does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Acute and chronic aquatic studies suggest a relatively low level of toxicity associated with this substance. No terrestrial toxicity studies were available for this substance.

B. Aquatic Toxicity

Acute Studies

There are no adequate aquatic toxicity studies on sorbitan monooleate polyoxyethylene derivative. Aquatic toxicity data has been read-across from sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5].

Table 3: Acute Aquatic Toxicity Studies on Sorbitan Monolaurate, Ethoxylated (1-6.5 Moles Ethoxylated) [CAS No. 9005-64-5]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Brachydanio rerio	96-hr LL_{50}	>100 [WAF]	2	ECHA
Pseudokirchneriella subcapitata	72-hr EL_{50}	58.84 [WAF]	2	ECHA

Chronic Studies

The 21-day NOELR (No-Observed-Effect-Loading-Rate) for sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5] in a Daphnia reproduction test was 10 mg/L WAF (ECHA) [Kl. score = 2].

The 72-hr EL_{10} for sorbitan monolaurate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-64-5] to *Pseudokirchneriella subcapitata* is 19.05 mg/L WAF (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for sorbitan monooleate polyoxyethylene derivative follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)L_{50}$ values are available for fish (>100 mg/L WAF) and algae (58.84 mg/L WAF). The EL_{10} or NOELR values from chronic studies are available for invertebrates (10 mg/L WAF) and algae (58.8 mg/L WAF). On the basis that the data consists of short-term and long-term studies from two trophic levels, an assessment factor of 50 has been applied to the lowest reported EL_{10} value of 10 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 0.2 mg/L [WAF].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 2.1 to 3.4 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (15.88/1500) \times 1000 \times 0.2$
$= 2.1$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (25.18/1500) \times 1000 \times 0.2$
$= 3.4$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 794 \times 0.02$
$= 15.88$

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 1,259 \times 0.02$
$= 25.18$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for sorbitan monooleate, ethoxylated (1-6.5 moles ethoxylated) [CAS No. 9005-65-6 based on the molecular connectivity index (MC) ranged from 794 to 1,259 L/kg (U.S. EPA, 2019).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATIVE AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sorbitan monooleate polyoxyethylene derivative is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on the estimated BCF values of 12.6 to 14.6 L/kg, sorbitan monooleate polyoxyethylene derivative does not meet the criteria for bioaccumulation.

The chronic toxicity data on sorbitan monooleate polyoxyethylene derivative are >0.1 mg/L WAF. The acute E(L)L_{50} values for sorbitan monooleate polyoxyethylene derivative are >1 mg/L WAF. Thus, sorbitan monooleate polyoxyethylene derivative does not meet the criteria for toxicity.

Therefore, sorbitan monooleate polyoxyethylene derivative is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Aquatic Acute Toxicity Category 3

B. Labelling

No signal word.

C. Pictogram

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.

Skin Contact
Wash with soap and water. Get medical attention if symptoms occur.

Inhalation
Treat symptomatically. Move to fresh air. Get medical attention if symptoms persist.

Ingestion
Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media
Water spray, dry chemical, foam, carbon dioxide.

Specific Exposure Hazards
None known.

Special Protective Equipment for Firefighters
Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions
Wear appropriate personal protective equipment.

Environmental Precautions
Not regarded as dangerous to the environment.

Steps to be Taken if Material is Released or Spilled
Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling
No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions
Wash hands thoroughly after handling.

Storage
Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for Polysorbate 80.

Engineering Controls
Good general ventilation should be used.

Personal Protection Equipment
Respiratory Protection:
Respiratory protection is not required.

Hand Protection:
Minimize skin contact.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Minimize eye contact.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Polysorbate 80 is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BIBRA [British Industrial Biological Research Association] (1981). A short-term 913 week) study in rats with polyoxyethylene (20) sorbitan monostearate. BIBRA Report No. 356/2/81; reviewed in EFSA (2015).

CIR [Cosmetic Ingredient Review] (1984). Final report on the safety assessment of Polysorbates 20, 21, 40, 60, 61, 65, 80, 81, and 85. Int. J. Toxicol. 3: 1–82.

Culver, P.J., Wilcox, C.S., Jones, C.M., and Rose, R.S.J. (1951). Intermediary metabolism of certain polyoxyethylene derivatives in man. I. Recovery of the polyoxyethylene moiety from urine and feces following ingestion of polyoxyethylene (40) mono-stearate. J. Pharmacol. Exp. Ther. 103: 377-381; reviewed in EFSA (2015).

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

EFSA [European Food Safety Authority]. (2015). Scientific Opinion on the re-evaluation of polyoxyethylene sorbitan monolaurate (E 432), polyoxyethylene sorbitan monooleate (E 433), polyoxyethylene sorbitan monopalmitate (E 434), polyoxyethylene sorbitan monostearate (E 435) and polyoxyethylene sorbitan tristearate (E 436) as food additives. EFSA J. 13(7):4152. Available at: https://www.efsa.europa.eu/en/efsajournal/pub/4152.

Fitzhugh, O.G., Bourke, A.R., Nelson, A.A., and Frawley J.P. (1959). Chronic oral toxicities of four steraric acid emulsifiers. Toxicol. Appl. Pharmacol. 1: 315-331.

Haseman, J.K., Arnold, J., and Eustis, S.L. (1990). Tumor incidences in Fischer 344 rats: NTP historical control data. In: Pathology of the Fischer Rat Reference and Atlas (G.A. Boorman, S.L. Eustis, M.R. Elwell, C.A. Montgomery, Jr., and W.F. MacKenzie, Eds.), pp. 555-564, Academic Press, San Diego, CA.

JECFA [Joint FAO/WHO Expert Committee on Food Additives] (1974). Toxicological evaluation of some food additives including anticaking agents, antimicrobials, antioxidants, emulsifiers and thickening agents. WHO Food Additive Series No. 5.

Jenssen, D., and Ramel, C. (1980). The micronucleus tests as part of a short-term mutagenicity test program for the prediction of carcinogenicity evaluated by 143 agents tested. Mutat. Res. 75: 191-202.

Kerwin, B.A. (2008). Polysorbates 20 and 80 used in the formulation of protein biotherapeutics: structure and degradation pathways. J. Pharm. Sci. 97: 2924-2935.

Kimura, T., Imamura, H., Hasegawa, K., and Yoshida, A. (1982). Mechanisms of toxicities of some detergents added to a diet and of the ameliorating effect of dietary fiber in the rat. J. Nutr. Sci. Vitamin. 28: 483-489; reviewed in EFSA (2015).

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lynch, B.S., Tischler, A.S., Capen, C., Munro, I.C., McGirr, L.M., McClain, R.M. (1996). Low digestible carbohydrates (polyols and lactose): significance of adrenal medullary proliferative lesions in the rats. Regul. Toxicol. Pharmacol. 23: 256-297.

Nelson, M., Poulos, T., Gongwer, L., and Kirschman, J. (1966). Preparations of carbon-14-labelled polyoxyethylene (20) sorbitan monolaurate and their metabolic fate in rats. J. Food Sci. 31: 253-258; reviewed in EFSA (2015).

NTP [National Toxicology Program]. (1992a). Toxicology and Carcinogenesis Studies of Polysorbate 80 (CAS No 9005-65-6) in F344/N Rats and B6C3F$_1$ Mice (Feed Studies), NTP TR 415, NIH Publication No. 92-3146. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health.

NTP [National Toxicology Program] (1992b). Abstract for TER91009 – Polyoxyethylene Sorbitan Monooleate (CASRN 9005-65-6). Developmental Toxicology of Polyoxyethylene Sorbitan Monooleate (CAS #9005-65-6) in Sprague-Dawley CD® Rats. NTIS# PB93-123026.

Oser, B.L., and Oser M. (1956a). Nutritional studies on rats on diets containing high levels of partial ester emulsifiers. I. General plan and procedures; growth and food utilization. J. Nutr. 60: 367–390; reviewed in JEFCA (1974) and EFSA (2015).

Oser, B.L., and Oser, M. (1956b). Nutritional studies on rats on diets containing high levels of partial ester emulsifiers. II. Reproduction and lactation. J. Nutr. 60: 489–505; reviewed in JEFCA (1974) and EFSA (2015).

Oser, B.L., and Oser, M. (1957a). Nutritional studies on rats on diets containing high levels of partial ester emulsifiers. III. Clinical and metabolic observations. J. Nutr. 61: 149-166; reviewed in JEFCA (1974) and EFSA (2015).

Oser, B.L., and Oser, M. (1957b). Nutritional studies on rats on diets containing high levels of partial ester emulsifiers. IV. Mortality and post-mortem pathology; general conclusions. J. Nutr. 61: 235-52 reviewed in JEFCA (1974) and EFSA (2015).

Nelson, M., Poulos, T., Gongwer, L., and Kirschman, J. (1966). Preparations of carbon-14-labelled polyoxyethylene (20) sorbitan monolaurate and their metabolic fate in rats. J. Food Sci. 31: 253-258; reviewed in EFSA (2015).

Treon, J.F., Gongwer, L.E., Nelson, M.F., and Kirschman, J.C. (1967). Physiologic and metabolic patterns of non-ionic surfactants. In: Chemistry, physics and application of surface active substances, 4th Edition. Edited by F. Asinger. Pp. 381-395, Gordon and Breach, London, England.

van Tellingen, O., Beijnen, J.H., Verweij, J., Scherrenburg, E.J., Nooijen, W.J., and Sparreboom, A. (1999). Rapid esterase-sensitive breakdown of polysorbate 80 and its impact on the plasma pharmacokinetics of docetaxel and metabolites in mice. Clin. Cancer Res. 5: 2918-2924.

TRIETHANOLAMINE

This dossier on triethanolamine presents the most critical studies pertinent to the risk assessment of triethanolamine in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-[bis(2-hydroxyethyl)amino]ethan-1-ol

CAS RN: 102-71-6

Molecular formula: $C_6H_{15}NO_3$ or $(CH_2OHCH_2)_3N$

Molecular weight: 149.19

Synonyms: Triethanolamine; 2,2',2"-nitrilotriethanol; 2,2',2"-nitrilotris[ethanol]; ethanol, 2,2',2"-nitrilotri- (8Cl); ethanol, 2,2',2"-nitrilotris- (9Cl); nitrilotriethanol; TEA; tris(beta-hydroxyethyl)amine; tris(2-hydroxyethyl)amine

SMILES: C(CO)N(CCO)CCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Triethanolamine

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colorless to pale-yellow liquid with an amine-like odor.	2	ECHA
Melting Point	20.5°C	2	ECHA
Boiling Point	336.1°C	2	ECHA
Density	1.12 g/cm^3 @ 20°C	2	ECHA
Vapor Pressure	Negligible	2	ECHA

Property	Value	Klimisch score	Reference
Partition Coefficient (log K_{ow})	-1.9 @ 25°C [Experimental]	2	ECHA
Water Solubility	>1,000 g/L @ 20°C	2	ECHA
Flash Point	179°C	2	ECHA
Auto flammability	324°C	2	ECHA
Viscosity	830.2 mm^2/s @ 20°C 181.5 mm^2/s @ 40°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Triethanolamine is readily biodegradable, and it has a low potential to bioaccumulate. Triethanolamine will not adsorb significantly to suspended solids and sediments in water and would be highly mobile in soil.

B. Biodegradation

Triethanolamine is readily biodegradable. In an OECD 301E test, there was 96% degradation after 19 days (ECHA). [Kl. score = 2]

Triethanolamine was completely degraded after incubation in municipal activated sludge for 1 or 5 days (West and Gonsior, 1996). The rate constants in all test batches for degradation and mineralization were reported to be >0.359. Thus, triethanolamine can be considered to be readily biodegradable. [Kl. score = 2]

C. Environmental Distribution

<u>Adsorption/desorption</u>
No experimental data are available for triethanolamine. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} value from log K_{ow} of -2.48 is 0.3046 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 10 L/kg.

D. Bioaccumulation

Triethanolamine has been tested in a bioconcentration flow-through fish (OECD 305) test using *Cyprinus carpio*. The BCF was determined to be <0.4 and <3.9 at

triethanolamine concentrations of 2.5 and 0.25 mg/L, respectively (ECHA). [Kl. score = 2]

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of triethanolamine by the oral, dermal, and inhalation routes is very low. Triethanolamine is not a skin or eye irritant; it is not a skin sensitizer to guinea pigs, but it may cause an allergic skin reaction in a small proportion of individuals. Repeated exposure by the oral route in rats showed no adverse effects. Repeated exposure by the inhalation caused effects to the respiratory tract and skin, respectively, in rats as a result of chronic irritation; but no target organs were identified from systemic exposure. Triethanolamine is not genotoxic, and lifetime oral and dermal studies in rats showed no clear carcinogenic effects. Developmental toxicity was seen in rats at oral doses that caused maternal toxicity.

B. Acute Toxicity

The oral LD_{50} in rats is 6,400 mg/kg (ECHA) [Kl. score = 2], and the dermal LD_{50} in rabbits is >2,000 mg/kg (ECHA) [Kl. score = 2]. No deaths seen in rats following an 8-hour exposure to a saturated vapor atmosphere [approximately 1.8 mg/m^3] (ECHA) [Kl. score = 2].

C. Irritation

Application of 0.5 mL to the skin of rabbits for 4 hours under occlusive conditions was not irritating. The mean of the 24, 48, and 72 hours erythema and edema scores were zero (ECHA). [Kl. score = 1]

Instillation of 0.1 mL into the eyes of rabbits were minimally irritating (Griffith *et al.*, 1980). [Kl. score = 2]

D. Sensitization

Triethanolamine was not considered a skin sensitizer when tested in a guinea pig maximization test (ECHA). [Kl. score = 1]

Patch test results with triethanolamine on patients from 1992 to 2007 were collected and evaluated. There were 85,098 patients that were tested with triethanolamine; of these, 323 (0.35%) patients tested positively to triethanolamine. The positive reactions that were interpreted as allergic seem to be caused by exposure to triethanolamine in cosmetics and/or topical therapeutic preparations possibly on damaged skin (Lessmann *et al.*, 2009).

E. Repeated Dose Toxicity

Oral

Male and female Cox CD rats were fed diets containing 0, 250, 500 or 1,000 mg/kg triethanolamine for 91 days. There were no effects that were considered treatment-related. The NOAEL for this study is 1,000 mg/kg-day (ECHA). [Kl. score = 2]

Inhalation

Male and female Wistar rats were exposed (nose-only) by inhalation to 0, 0.02, 0.1, or 0.5 mg/L triethanolamine aerosol 6 hours/day, 5 days/week for 28 days. There was no mortality; the only clinical signs were reddish crusts on the nasal edges in the 0.5 mg/L animals during the second half of the exposure period. Body weights and body weight gain were similar across all groups. There was no treatment-related changes in the hematology parameters, clinical chemistry, and neurobehavioral endpoints. Local inflammatory changes were observed in the submucosa of the larynx region. In both sexes, there was a tendency for a concentration-dependent increase in incidence and severity of the inflammatory lesions, with the effects greater in males than females. The NOAEC for systemic effects is 0.5 mg/L; the NOAEC for localized effects is 0.02 mg/L (ECHA) [Kl. score = 1].

Dermal

Male and female F344 rats were given dermal applications of 0, 125, 250, 500, 1,000, and 2,000 mg/kg triethanolamine 5 days/week for 90 days. There was deaths during the study. Body weight gain was significantly reduced (-33%) in the 2,000 mg/kg males compared to controls. Body weight gain was also significantly reduced (-13% to 36%) for the ≥125 mg/kg females. The mean final body weights of the 2,000 mg/kg males and females were significantly reduced. The only treatment-related clinical signs occurred at the site of dermal application. Brain weights relative to body weights were significantly elevated in the 2,000 mg/kg animals; because absolute brain weights were unaffected, the changes in brain weights is likely due to reduced body weights in these animals. Absolute kidney weights were increased in the ≥1,000 mg/kg animals; relative kidney weights were elevated in the ≥250 mg/kg males and ≥1,000 mg/kg females. Absolute and relative spleen weights were lower in the 2,000 mg/kg females; relative spleen weights were elevated in the ≥1,000 mg/kg males. Absolute and relative thymus weights were increased in the 2,000 mg/kg males. Relative liver weights were increased in the 500 and 1,000 mg/kg males. Absolute and relative lung weights were lower in the 2,000 mg/kg males. Relative testes weights were increased in the 2,000 mg/kg males. Hematological changes were seen in the 2,000 mg/kg animals and were considered to be due to an inflammatory response from dermal irritation at the application site. Elevated SGOT levels were noted in the 250 and 2,000 mg/kg males; and mean SGPT levels were significantly increased in the 2,000 mg/kg males. Elevated serum urea nitrogen, albumin, SGOT, and SGPR levels were noted in the 2,000 mg/kg females. At

study termination, the specific gravity of urine was elevated in the 2,000 mg/kg males; urine protein levels for the ≥500 mg/kg males were significantly lower. The specific gravity of urine was elevated in the ≥1,000 mg/kg females; urine glucose concentrations were also increased in these two dose groups. Apart for skin lesions at the site of application, there were no treatment-related histopathologic changes. The NOAEL for localized effects is 125 mg/kg-day based on chronic-active inflammation and acanthosis at the site of application in males. The NOAEL for systemic toxicity is 125 mg/kg-day based on increased relative kidney weights in males (ECHA) [Kl. score = 2].

F. Genotoxicity

In Vitro Studies

The findings from the *in vitr*o genotoxicity studies on triethanolamine are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Triethanolamine

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	Mortelsman *et al.* (1986); ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	2	Galloway *et al.* (1987); ECHA
Sister chromatid exchange (CHO cells)	-	-	2	Galloway *et al.* (1987); ECHA

*+, positive; -, negative

In Vivo Studies

Male and female B6C3F_1 mice were given dermal applications of triethanolamine, 5 days/week for 13 weeks. There were no increase in the frequency of micronucleated erythrocytes in the peripheral blood (NTP, 2004).

Triethanolamine did not induce sex-linked recessive lethal mutations in germ cells of adult male *Drosophila melanogaster* exposed by feeding or injection (Yoon *et al.*, 1985).

G. Carcinogenicity

Oral

Male and female F344 were given triethanolamine in their drinking water for two years. The doses were 0, 1, and 2%; but starting on week 69, the doses for females were 0.5 and 1%. The estimated daily intakes for 1 and 2% dose groups were approximately 667 and 1,333 mg/kg-day; and the estimated daily intakes for the 0.5% and 1% in females were approximately 333 and 667 mg/kg-day. There were no statistically significant increases in the incidence of tumors between treated and control groups when analyzed by Chi-square test. However, there was an increase in nephrotoxicity which appeared to have an adverse effect on the life expectancy of the treated animals, especially the females. So, an age-adjusted statistical analysis was conducted. There was a positive trend ($p<0.05$) in the occurrence of liver tumors in males and of uterine endometrial sarcomas and renal-cell adenomas in females. These tumors have been observed spontaneously in this strain of rats, and their incidences in the controls were lower than historical controls for other laboratories. The results may indicate that a positive trend in the occurrence of these tumors is not attributable to triethanolamine exposure. Increased incidence of kidney tumors in the high-dose females may have been connected with kidney damage. Histopathologic examination of the kidney effects observed in the treated groups, especially the high-dose females, showed acceleration of chronic nephropathy. Also, mineralization of the renal papilla, nodular hyperplasia of the pelvic mucosa, and pyelonephritis with or without papillary necrosis were also observed (Maekawa *et al.*, 1986; ECHA) [Kl. score = 2]

Male and female $B6C3F_1$ mice were given in their drinking water 0, 1 or 2% triethanolamine (0 and approximately 1,600 and 3,200 mg/kg-day) for 82 weeks. Mortality, organ weights and tumor incidences were similar between treated and control animals (Konishi *et al.*, 1992; ECHA). [Kl. score = 2]

Inhalation

No studies are available.

Dermal

Male and female F344 rats were given dermal applications of triethanolamine, 5 days/week for two years. The doses were: 0, 32, 63 or 125 mg/kg-day for males, and 0, 63, 125 or 250 mg/kg-day for females. There were no treatment-related carcinogenic effects in either sexes (NTP, 1999). [Kl. score = 1]

Male and female $B6C3F_1$ mice were given dermal applications of triethanolamine, 5 days/week for two years. The doses were: 0, 200, 630 and 2,000 mg/kg-day for males, and 0, 100, 300 and 1,000 mg/kg-day for females. In females, there was some evidence of carcinogenicity activity based on increased incidences of hepatocellular adenomas. In males, there was equivocal evidence of carcinogenicity activity based on the incidence of liver hemangiosarcomas (NTP, 2004). [Kl. score = 1]

H. Reproductive/Developmental Toxicity

In a reproductive and developmental toxicity screening (OECD 421) study, male and female Wistar rats were dosed by oral gavage with 0, 100, 300 or 1,000 mg/kg-day triethanolamine. Most of the 1,000 mg/kg-day animals and one 100 mg/kg-day animals showed transient salivation for a few minutes immediately after each treatment. This effect was considered to be induced by the unpalatability of the test substance or from local irritation of the upper digestive tract. Body weight gain was slightly lower in the 1,000 mg/kg-day females during gestation and was considered to be caused by the increased postimplantation loss rather than by a systemic effect of the test substance. In the 1,000 mg/kg-day group, there were lower mean number of implantation sites, increased postimplantation loss, and lower average litter size. There were no treatment-related effects in the F_1 pups. The NOAEL for systemic toxicity is 1,000 mg/kg-day. The NOAEL for reproductive toxicity is 1,000 mg/kg-day. The NOAEL for developmental toxicity is 300 mg/kg-day (ECHA). [Kl. score = 1]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for triethanolamine follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

There were no effects seen in a 91-day dietary study in rats, with a NOAEL of 1,000 mg/kg-day (ECHA). This NOAEL will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 1,000/(10 x 10 x 1 x 10 x 1) = 1,000/1,000 = <u>1.0 mg/kg-day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (1.0 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

There were no carcinogenic effects in male and female mice given triethanolamine in their drinking water for 82 weeks (Konishi et al., 1992). In a two-year drinking water study, age-adjust tumor incidence showed increased liver tumors in males, and uterine endometrial sarcomas and renal tubule adenomas in females. These tumors were not attributed to triethanolamine exposure because, in comparison with historical control incidences, the tumors reflected low incidences in the control groups rather than increased incidences in the exposed groups.

In dermal carcinogenicity studies, there was no evidence of carcinogenicity in male and female rats (NTP, 1999). In female mice, there was some evidence of carcinogenicity activity based on increased incidences of hepatocellular adenomas. In male mice, there was equivocal evidence of carcinogenicity activity based on the incidence of liver hemangiosarcomas (NTP, 2004).

A cancer reference value for triethanolamine was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Triethanolamine does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Triethanolamine has low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies
Table 3 lists the results of acute aquatic toxicity studies conducted on triethanolamine.

Table 3: Acute Aquatic Toxicity Studies on Triethanolamine

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-h LC_{50}	11,800	2	ECHA
Ceriodaphnia dubia	48-h EC_{50}	610	2	Warne and Schifko, 1999
Desmodesmus subspicatus	72-h EC_{50} EC_{10}	512 (neutralized) 216 (un-neutralized) 26 (neutralized)	2	ECHA

Chronic Studies
In a 21-day *Daphnia* reproduction test, the NOEC for mortality is 16 mg/L, the NOEC for reproduction rate was 125 mg/L, and the NOEC for reproduction on the appearance of first offspring was 250 mg/L (Kuehn *et al.*, 1989). [Kl. score = 2]

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for triethanolamine follow the methodology discussed in DEWHA (2009).

PNEC water
Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (11,800 mg/L), invertebrates (610 mg/L), and plants (512 mg/L). Results from chronic studies are available for invertebrates (NOEC = 16 mg/L) and algae (EC_{10} = 26 mg/L). On the basis that the data consists of chronic studies for two trophic levels,

an assessment factor of 50 has been applied to the lowest reported EC_{10} of 16 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 0.32 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.25 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.99/1280) \times 1000 \times 0.32$
$= 0.25$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.4/1000 \times 2400]$
$= 0.99$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 10 \times 0.04$
$= 0.4$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for triethanolamine calculated from EPISUITE™ using MCI is 10 L/kg .
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.04 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.2/1500) \times 1000 \times 0.32$
$= 0.04$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 10 \times 0.02$
$= 0.2$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for triethanolamine calculated from EPISUITE™ using the MCI is 10 L/kg .
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Triethanolamine is readily biodegradable; thus it does not meet the screening criteria for persistence.

The BCF values for triethanolamine in fish was <3.9; thus it does not meet the criteria for bioaccumulation.

The NOEC or EC_{10} values from chronic aquatic toxicity studies on triethanolamine is >0.1 mg/L. Thus triethanolamine does not meet the criteria for toxicity.

The overall conclusion is that triethanolamine is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

Danger
According to the classification provided by companies to ECHA in REACH registrations this substance causes serious eye damage and is suspected of damaging fertility or the unborn child.

Additionally, the classification provided by companies to ECHA in CLP notifications identifies that this substance causes serious eye irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact
Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If effects occur, get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact
Remove contaminated clothing. Wash thoroughly with soap and water. Seek medical attention if irritation persists.

Inhalation
If inhaled, remove from area to fresh air. Give artificial respiration if victim is not breathing. Get medical attention.

Ingestion
Rinse mouth with water and then drink plenty of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media
Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: nitrogen oxides, carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters
Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes, and clothing.

Environmental Precautions
Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled
For large amounts: dike spillage and pump off product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling
Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage
Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
The workplace exposure standard for triethanolamine in Australia is 5 mg/m^3 as an 8-hour TWA, with a sensitization notation.

Engineering Controls
Good general ventilation should be used. Use local exhaust ventilation, or other engineering controls to maintain airborne levels below exposure limit guidelines.

Personal Protection Equipment
Respiratory Protection:
Use respiratory protection in case of vapor or aerosol release.

Hand Protection:
Chemical resistant protective gloves.

Skin Protection:
Body protection must be chosen depending on activity and possible exposure.

Eye protection:
Safety glasses with side-shields.

Other Precautions:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Triethanolamine is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Galloway, S.M., Armstrong, M.J., Reuben, C., Colman, S., Brown, B., Cannon, C., Bloom, A.D., Nakamura, F., Ahmed, M., Duk, S., Rimpo, J., Margolin, B.H., Resnick, M.A., Anderson, B., and Zeiger, E. (1987). Chromosome aberrations and sister chromatid exchanges in Chinese hamster ovary cells: Evaluations of 108 chemicals. Environ. Mol. Mutag. 10 (Suppl. 10): 1-175.

Griffith, J.F., Nixon, G.A., Bruce, R.D., Reer, P.J., and Bannan, E.A. (1980). Dose-response studies with chemical irritants in the albino rabbit eye as a basis for selecting optimum testing conditions for predicting hazard to the human eye. Toxicol. Appl. Pharmacol. 55: 501-513.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Konishi, Y., Denda, A., Uchida, K., Emi, Y., Ura, H., Yokose, Y., Shiraiwa, K., and Tsutsumi, M. (1992). Chronic toxicity carcinogenicity studies of triethanolamine in B6C3F1 mice. Fundam. Appl. Toxicol. 18: 25-29.

Kuehn, R., Pattard, M., Pernak, K.D., and Winter, A. (1989). Results of the harmful effects of water pollutants to *Daphnia magna* in the 21-day reproduction test. Water Res. 23: 501-510.

Lessmann, H., Uter, W., Schnuch, A., Geier, J. (2009). Skin sensitizing properties of the ethanolamines mono-, di- and triethanolamine. Data analysis of a multicenter surveillance network (IVDK) and review of literature. Contact Dermatitis 60: 243-255.

Maekawa, A., Onodera, H., Tanigawa, H., Furuta, K., Kanno, J., Matsuoka, C., Ogiu, T., and Hayashi, Y. (1986). Lack of carcinogenicity of triethanolamine in F344 rats. J. Toxicol. Environ. Health 19: 345-357' reviewed in ECHA REACH database.

Mortelsman, K., Haworth, S., Lawlor, T., Speck, W., Tainer, B., and Zeiger, E. (1986). *Salmonella* mutagenicity tests: II. Results from the testing of 270 chemicals. Environ. Mutagen. 8 (Suppl. 7): 1-119.

NTP (1999). NTP Technical Report on the Toxicology and Carcinogenesis Studies of Triethanolamine (CAS No. 102-71-6) in F344/N Rats and B6C3F$_1$ Mice (Dermal Studies). NTP TR 449, NIH Publication No. 00-3365. National Toxicology Program, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Research Triangle Park, NC.

NTP (2004). NTP Technical Report on the Toxicology and Carcinogenesis Studies of Triethanolamine (CAS No. 102-71-6) in B6C3F$_1$ Mice (Dermal Study). NTP TR 518, NIH Publication No. 04-4452. National Toxicology Program, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, Research Triangle Park, NC.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Warne, M.S.J., and Schifko, A.D. (1999). Toxicity of laundry components to a freshwater *Cladoceran* and their contribution to detergent toxicity. Ecotoxicol. Environ. Saf. 44: 196-206.

West, R.J., and Gonsior, S.J. (1996). Biodegradation of triethanolamine. Environ. Toxicol. Chem. 15: 472-480.

Yoon, J.S., Mason, J.M., Valencia, R., Woodruff, R.C., and Zimmering, S. (1985). Chemical mutagenesis testing in *Drosophila*. IV. Results of 45 coded compounds tested for the National Toxicology Program. Environ. Mutagen. 7: 349-367.

TRIBUTYL TETRADECYL PHOSPHONIUM CHLORIDE

This dossier on tributyl tetradecyl phosphonium chloride (TTPC) presents the most critical studies pertinent to the risk assessment of TTPC in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Tributyl(tetradecyl)phosphonium;chloride

CAS RN: 81741-28-8

Molecular formula: $C_{26}H_{56}PCl$

Molecular weight: 435.15

Synonyms: Tributyl tetradecyl phosphonium chloride; TTPC; tri-n-butyltetradecylphosphonium chloride; Bellacide 350; Bellacide 355

SMILES: CCCCCCCCCCCCCC[P+](CCCC)(CCCC)CCCC.[Cl-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of TTPC

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear, colorless liquid	4	BWA Additives (2016)
Boiling Point	100°C*	4	BWA Additives (2016)
Specific Gravity	0.98 – 1.00 @ 20°C	4	BWA Additives (2016)
Partition Coefficient (log K_{ow})	2.45	4	BuruEnergy

Property	Value	Klimisch score	Reference
Viscosity	55-65 mm^2/s @ 25°C	4	BWA Additives (2016)

*5% aqueous solution of TTPC

TTPC is a non-oxidizing biocide. Information on TTPC in this dossier has been obtained from BWA™ Water Additives, a producer of TTPC. BWA™ Water Additives produces a 5% or 50% aqueous solution of TTPC, which is sold under the product names Bellacide® 355 and Bellacide® 350, respectively.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

TTPC is stable over a wide pH range and is not susceptible to photodegradation. TTPC is biodegradable, but not readily biodegradable. It will strongly adsorb to soil and sediment. TTPC is not expected to bioaccumulate.

B. Abiotic Degradation

Hydrolysis
TTPC is stable over a wide pH range (BuruEnergy). [Kl. score = 4]

Photolysis
TTPC is not susceptible to photodegradation. (BuruEnergy). [Kl. score = 4]

C. Biodegradation

TTPC was not readily biodegradable in an OECD 301 test (BuruEnergy). [Kl. score = 4]

A die-away [simulation] test was conducted with radiolabelled TTPC for 168 hours at concentration of 0.31 mg/L. The first-order rate constant was 0.69/hour and the half-life was 6.6 hours. After 24 and 168 hours, degradation was >81% and >98%, respectively (BuruEnergy). [Kl. score = 4]

TTPC was evaluation in a simulation test over a 40-day period using double ^{14}C labeled TTPC. In activated sludge, there was >40% degradation after 30 days with 50 ppb TTPC and >30% degradation after 7 days with 5 ppb TTPC. In river water, there was >20% after 35 days with 5 ppb TTPC. In sea water, there was >30% degradation after 35 days with 5 ppb TTPC (BuruEnergy). [Kl. score = 4]

D. Environmental Distribution

Adsorption/desorption

TTPC strongly adsorbs to soil. In a study involving three different soil types (sand, silt, and clay), 93 to 96% of TTPC adsorbed to soil (BuruEnergy). [Kl. score = 4]

No experimental studies are available for determining the K_{oc} of TTPC. Using KOCWIN in EPISUITE™ (EPA, 2017), the estimated K_{oc} value for TTPC using the MCI method is 4.555 x 10^7 L/kg.

E. Bioaccumulation

No bioaccumulation studies are available on TTPC. TTPC is not expected to bioaccumulate based on the experimental log K_{ow} of 2.45 (BuruEnergy). [Kl. score = 4]

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

TTPC exhibits moderate acute toxicity by the oral route, but is highly toxic by the inhalation route. It is corrosive to the skin and eyes, but it is not a skin sensitizer. No target organ effects were noted in a 90-day rat drinking water study. TTPC was not mutagenic in a bacterial reverse mutation (Ames) test. There are no carcinogenicity studies on TTPC. In rats, developmental toxicity was shown to occur at oral dose levels that were not maternally toxic; whereas, in rabbits, developmental toxicity occurred only at maternally toxic doses.

B. Acute Toxicity

An oral LD_{50} in rats for Bellacide 350 (50% aq. solution of TTPC) was reported to be >1,002 mg/kg (BWA Additives, 2011) [Kl. score = 4]. An oral LD_{50} in rats for Bellacide 355 (5% aqueous solution of TTPC) was reported to be >4,000 mg/kg (BWA Additives, 2009) [Kl. score = 4].

The 4-hour inhalation LC_{50} in male and female rats for a 50% aq. solution of TTPC was <0.05 mg/L (aerosol). The mass median aerodynamic diameter for the aerosol was 1.93 µm (Cytec, 2012) [Kl. score = 1]. The 1-hour inhalation LC_{50} in male and female rats for a 50% aq. solution of TTPC is 0.227 mg/L (aerosol). The mass median aerodynamic diameter for the aerosol was 1.92 µm (Cytec, 2013) [Kl. score = 1].

C. Irritation

Both Bellacide 350 (50% aq. solution TTPC) and Bellacide 355 (5% aq. solution TTPC) are considered to be corrosive to the skin and eyes (BWA Additives, 2011; 2015). [Kl. score = 4]

D. Sensitization

TTPC is not considered to be a skin sensitizer (BWA Additives, 2011; 2015). [Kl. score = 4]

E. Repeated Dose Toxicity

Oral
A 90-day rat drinking water study has been conducted on a product containing TTPC. The LOAEL for the active ingredient (TTPC) is 27.2 and 32.3 mg/kg-day in males and females, respectively, based on various clinical signs and significantly reduced body weights, feed and water consumption. The NOAEL for this study is 8.66 mg/kg-day (EPA, 2006). [Kl. score = 2]

Inhalation
No data are available.

Dermal
No data are available.

F. Genotoxicity

In Vitro Studies

TTPC was not mutagenic in a reverse mutation bacterial (Ames) test (BWA Additives, 2015). [Kl. score = 4]

In vivo Studies

No studies are available.

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Female Tif:RAIf(SPF) rats were dosed by oral gavage with 0, 20, 60, or 120 mg/kg Belclene® [50% active ingredient: TTPC] during gestational days (GD) 6 through 15. In the high-dose group, there were two possible treatment-related spontaneous deaths (GD 9 and 14) and another death on GD 15 due to an intubation error. Clinical signs included dyspnea in one mid-dose and 4 high-dose animals, and vaginal bleeding in one mid-dose female on GD 15. In the high-dose group, maternal body weight gain was significantly lower during the treatment period (GD 6-15) and throughout the gestational period (GD 0-20). Mean food consumption was significantly reduced during GD 6-11 for both the mid- and high-dose animals. The number of females with implantations and the number of implantations/females were similar across all groups. Embryonic and fetal deaths were similar between treated and control groups. There were no soft tissue changes. There was an increased incidence of incomplete ossification of the 5th sternebra in the mid- and high-dose groups. The NOAELs for maternal and developmental toxicity for the active ingredient TTPC in this study is 30 and 10 mg/kg-day, respectively (EPA, 2006). [Kl. score = 2]

Female chinchilla rabbits were dosed by oral gavage with 0, 7.5, 22.5, or 45 mg/kg Belclene® [50% active ingredient: TTPC] during gestational days (GD) 6 through 18. In the mid- and high-dose groups, body weight gain was significantly reduced during GD 6-18 and feed consumption was reduced during GD 6-11. Fetal body weights were significantly reduced in the mid-(males only) and high-dose dose groups. There was also an increased incidence of delayed ossification of the hindlimb phalangeal nuclei in the mid- and high-dose groups. The NOAEL for maternal and developmental toxicity for the active ingredient TTPC in this study is 3.75 mg/kg-day (EPA 2006). [Kl. score = 2]

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for TTPC follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>

The NOAEL from a rat 90-day drinking water study based on various clinical signs and significantly reduced body weight and reduced feed and water consumption is 8.66 mg a.i./kg-day (EPA, 2006). This NOAEL will be used to derive the oral Reference Dose.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1

Oral RfD = 8.66/(10 x 10 x 1 x 10 x 1) = 8.66/1000 = 0.009 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,
Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.009 x 70 x 0.1)/2 = 0.03 mg/L

B. Cancer

No carcinogenicity studies are available on TTPC. Thus, a cancer reference dose was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

TTPC does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

TTPC has a very high acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on TTPC.

Table 2: Acute Aquatic Toxicity Studies on TTPC

Test Species	Endpoint	Results (µg/L)	Klimisch score	Reference
Bluegill sunfish	96-h LC_{50}	58.6	2	ECOTOX
Common Carp	96-h LC_{50}	87	2	ECOTOX
Rainbow trout	96-h LC_{50}	490	2	ECOTOX
Rainbow trout	96-h LC_{50}	200	2	ECOTOX
Daphnia magna	48-h EC_{50}	25.2	2	ECOTOX
Selenastrum capricornutum	72-h EC_{50}	19	4	BuruEnergy

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

Table 3 lists the avian toxicity studies conducted on TTPC.

Table 3: Avian Toxicity Studies on TTPC

Test Species	Endpoint	Results	Kl. score	Reference
Bobwhite Quail	8-d dietary	LC_{50}: 4,215 ppm NOEL: 1,980 ppm	2	ECOTOX
Mallard Duck	8-d dietary	LC_{50}: 3,663 ppm NOEL: 1,780 ppm	2	ECOTOX
Mallard Duck	14-d oral	LD_{50}: 232 mg/kg	2	ECOTOX

Test Species	Endpoint	Results	Kl. score	Reference
	gavage	NOEL: <178 mg/kg		

D. Calculation of PNEC

The PNEC calculations for TTPC follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (58.6 µg/L), *Daphnia* (25 µg/L), and algae (19 µg/L). No chronic toxicity studies are available on TTPC. On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the effect concentration of 19 µg/L for algae. The $PNEC_{aquatic}$ is calculated to be 0.019 µg/L (1.9 x 10^{-5} mg/L).

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 12,982 µg/kg (13.0 mg/kg) sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (874{,}561/1280) \times 1000 \times 0.019$
$= 12{,}982$

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]

$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 1{,}822{,}000/1000 \times 2400]$
$= 874{,}561$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$
$= 45{,}550{,}000 \times 0.04$
$= 1{,}822{,}000$

Where:
K_{oc} = organic carbon normalized distribution coefficient (L/kg). The K_{oc} for TTPC calculated from EPISUITE™ using the MCI method is 4.555×10^7 L/kg.
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 11,539 µg/kg (11.5 mg/kg) soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (911{,}000/1500) \times 1000 \times 0.019$
$= 11{,}539$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 45{,}550{,}000 \times 0.02$
$= 911{,}000$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for TTPC calculated from EPISUITE™ using the MCI method is 4.555×10^7 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

In a simulation test using river water, there was >20% after 35 days; however, no information is available on longer time points. TTPC is not readily biodegradable; thus it meets the screening criteria for persistence.

The log K_{ow} for TTPC is 2.45. Thus, TTPC does not meet the screening criteria for bioaccumulation.

There are no chronic aquatic toxicity studies available on TTPC. The lowest acute E(L)C_{50} value for TTPC is <1 mg/L in algae. Thus TTPC meet the criteria for toxicity. Therefore, TTPC is not a PBT substance.

IX. CLASSIFICATION AND LABELLING (Australia GHS)

A. Classification

Acute Toxicity Category 4 [Oral]
Acute Toxicity Category 1 [Inhalation]
Skin Corrosion Category 1
Eye Damage Category 1
STOT RE Category 2
Aquatic Acute Category 1
Aquatic Chronic Category1

B. Labelling

Danger

C. Pictogram



In addition to the hazard statements corresponding the GHS classifications, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>
Flush with plenty of fresh water for 15 minutes holding eyelids open, lifting eyelids occasionally to ensure complete removal of the product. DO NOT allow rubbing of eyes or keeping eyes closed. Remove contact lenses. Seek medical advice.

Skin Contact
Rinse with soap and plenty of water for several minutes. Remove contaminated clothing. Seek medical attention immediately.

Inhalation
Remove person to fresh air. Apply artificial respiration if not breathing. Seek medical attention.

Ingestion
Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting. Seek medical advice immediately.

B. Fire Fighting Information

Extinguishing Media
Suitable Extinguishing Media: carbon dioxide, water spray, foam, dry chemical.

Specific Exposure Hazards
Containers may explode when heated. May form explosive mixtures with strong acids. Hazardous combustion products may include the following materials: carbon monoxide, carbon dioxide, phosphorus oxides, chlorine.

Special Protective Equipment for Firefighters
Full protective clothing and approved self-contained breathing apparatus required for firefighting personnel.

C. Accidental Release Measures

Personal Precautions
Use appropriate protective equipment and avoid direct contact. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate the area before entry.

Environmental Precautions
Prevent spills from entering storm drains or sewers and contact with soil.

Steps to be Taken if Material is Released or Spilled
Use an absorbent material to recover as much product as possible, then, rinse the affected area with water to dilute the residue. Disposal of leftover product and used containers should be carried out in accordance with all local, state and federal regulations.

D. Storage And Handling

General Handling
Wear appropriate personal protective equipment. Avoid contact with eyes, skin or clothing. Avoid breathing mist, vapours or spray. Use only with adequate ventilation. Wash hands after use. Launder contaminated clothing.

Storage
Keep container closed when not in use. Store in a cool well ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards
Workplace Australia has not established an occupational exposure standard for TTPC.

Engineering Controls
Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment
Respiratory Protection: Use a mask or approved air-purifying respirator with appropriate cartridge or canister in spray applications or in confined spaces.

Hand Protection: Wear impervious gloves to prevent skin contact and absorption of this material. Rubber or Neoprene gloves may afford adequate skin protection.

Skin Protection: Wear appropriate clothes (*i.e*., coveralls). Use non-slip footwear.

Eye protection: Wear eye protection in situations where splash or thick mists are possible.

Other Precautions: Avoid contact with skin, eyes and clothing. When using, do not eat or drink. Wash hands thoroughly with soap and water before eating or drinking. Remove contaminated clothing and launder before reuse.

F. Transport Information

UN2922 CORROSIVE LIQUID, TOXIC N.O.S. (contains tributyltetradecyl phosphonium chloride)
Class 8 and 6.1
Packing Group: II

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BWA Water Additives (2011). Material Safety Data Sheet for Bellacide 350, SDS No.: 10794. BWA Water Additives, Report Date: 13/01/2011. Available at: http://biosourceinc.com/images/Bellacide_350_MSDS,_2011.pdf.

BWA Water Additives (2015). Safety Data Sheet for Bellacide 355, BWA Water Additives, Report Date: 10/03/2009. Available at: http://towerwater.com/wp-content/uploads/2014/08/BELLICIDE-355-Label-SDS.pdf.

BWA Water Additives (2016). Technical Data Sheet for Bellacide® 355. Available at: http://www.wateradditives.com/files/products/tech_data_sheets/Bellacide%20355_Technical%20Data%20Sheet_Oil%20Gas_8.5x11.pdf.

BuruEnergy (Environmental Properties of Proposed Biocide BE-9. BuruEnergy. Accessed at: http://www.buruenergy.com/wp-content/uploads/BE-Environmental-Properties-of-Proposed-Biocide-BE-91.pdf.

Cytec (2012). TSCA Section 8(e) submission letter to U.S. EPA with attachment titled "Acute Inhalation Toxicity Study in Rats – Limit Test", conducted at Product Safety Labs, Laboratory Study #34778. DCN #89130000015. Available at: https://yosemite.epa.gov/oppts/epatscat8.nsf/by+Service/E34D6235E54FA93785257B24006EEF4F/$File/89130000015.pdf.

Cytec (2013). TSCA Section 8(e) submission letter to U.S. EPA with attachment titled "Acute Inhalation Toxicity Study in Rats", conducted at Product Safety Labs, Laboratory Study #35656. DCN #89130000015. Available at: https://yosemite.epa.gov/oppts/epatscat8.nsf/by+Service/CA9FA94DCF6D9C7D85257B3D00514E05/$File/89130000257.pdf.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECOTOX. U.S. Environmental Protection Agency (EPA) ECOTOX Database: http://cfpub.epa.gov/ecotox/.

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. Environmental Protection Agency [EPA] (2006). Memorandum: Agency's Response to the Registrant Response for Acute Neurotoxicity and Repeated Exposure Inhalation Study and Determination of Inhalation MOE* and Developmental Toxicity Review for: Belclene 350 [Tri-n-butyl tetradecyl phosphonium chloride]. Office of Prevention, Pesticides and Toxic Substances, United States Environmental Protection Agency, June 27, 2006. Accessed at: http://www3.epa.gov/opp00001/chem_search/cleared_reviews/csr_PC-128824_27-Jun-06_a.pdf.

U.S. Environmental Protection Agency [EPA] (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ULEXITE

This dossier on ulexite presents the most critical studies pertinent to the risk assessment of ulexite in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium-calcium pentaborate octahydrate

CAS RN: 1319-33-1

Molecular formula: $(NaCaB_5O_6(OH)_6 \bullet 5H_2O)$

Molecular weight: 405 g/mol

Synonyms: Ulexite; sodium-calcium pentaborate octahydrate

Smiles: B1(OB2OB(O1)OB(O2)OB([O-])[O-])[O-].O.O.O.O.O.O.O.O.[Na+].[Ca+2]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Commercially Available Ulexite

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, granular, ground or powder form	4	Etimine USA, Inc. (2016)
Melting Point	870°C	4	Etimine USA, Inc. (2016)
Boiling Point	Not Applicable	-	-
Bulk Density	1,410 to 1,500 kg/m^3	4	Etimine USA, Inc. (2016)
Water solubility	26.67% as dissolved Ulexite @ 25°C by weight of solution	4	American Borate Company (2016)

Ulexite is a naturally-occurring mineral that is slightly soluble in water. Limited measured data are available for ulexite. In a study investigating the relative rates of boron from soluble and controlled-release boron fertilizers, ulexite showed releases of boron of 20% in just under 10 weeks; 40% in approximately 25 weeks; 60% by 40 weeks; and 80% by 60 weeks (Broschat, 2008). In the environment, borates will dissociate and/or hydrolyse to release boron as boric acid [$B(OH)_3$ (also formulated as H_3BO_3)] and/or borate anions. Therefore, the information presented within this dossier is for boron (CAS No. 7440-42-8).

III. ENVIRONMENTAL FATE PROPERTIES

Boron is found almost exclusively in the environment in the form of boron-oxygen compounds, which are often referred to as borates. In the environment, borates and compounds of boric acid will dissociate and/or hydrolyse to form the same boron species. For example, when borax dissolves in dilute solutions, it dissociates into Na+ ions and the tetraborate anion ($B_4O_5(OH)_4^{2-}$). Boric acid ($B(OH)_3$) is formed following acid catalysed hydrolysis of the tetraborate anion. Under alkaline conditions, dilute solutions of the tetraborate anion depolymerise rapidly to the mononuclear borate anion ($B(OH)_4^-$) (DoEE, 2017).

Boron is an inorganic, elemental compound and can therefore not be biodegraded by micro-organisms or other biotic-related processes (ECHA).

The WHO (1998) review of boron noted that highly water-soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated (ECHA).

Bioconcentration factors of < 0.1 to 10.5 L/kg have been reported from laboratory tests of fish and oysters (Thompson et al. 1976). Saiki et al. (1993) measured boron levels in aquatic food chains and observed the highest concentrations of boron in detritus and filamentous algae. Invertebrates and fish had lower concentrations, indicating that bioaccumulation was not occurring. Based on these data, boron does not bioaccumulate in the aquatic environment (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

No information is available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No values were derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ulexite does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no mammalian or aquatic toxicity studies on ulexite. Toxicity for boron is provided within this section.

Boron is of a low toxicity concern to aquatic organisms. Although boron is required by plants at low concentrations, at high concentrations it is toxic. In Australia, it is generally accepted that boron toxicity will pose a risk to terrestrial plants when soil concentrations exceed 15 mg/kg of extractable boron. The phytotoxicity of boron is dependent on the plant species and soil type (DoEE, 2017).

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies on boron.

Table 2: Acute Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
P. promelas	4-day LC_{50}	79.7 mg/B/L	2	ECHA
Freshwater invertebrates	48-hr LC_{50}	64 to >544 mg/B/L	2	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	52.4 mg/B/L	2	ECHA

1 – CAS No. 7440-42-8

Chronic Studies

Table 3 lists the results of chronic aquatic toxicity studies on boron.

Table 3: Chronic Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Micropterus salmoides	4d-EC_{10}	36.8 mg/B/L	2	ECHA
Oncorhynchus mykiss	long term NOEC-LOEC	19.2. mg/B/L	2	ECHA
Brachydanio rerio	long term NOEC-LOEC	36.mg/B/L	2	ECHA
Pimephales promelas	long term NOEC-LOEC	21.3 mg/B/L	2	ECHA
Daphnia magna	NOEC	13.9 mg/B/L	2	ECHA
Hyalella Azteca	NOEC	6.3 mg/B/L	2	ECHA
Chironomus riparius	NOEC	20.1 mg/B/L	2	ECHA
Brachionus calyciflorus	NOEC	24.6 mg/B/L	2	ECHA
Lampsilis siliquoidea	NOEC	30 mg/B/L	2	ECHA

1 – CAS No. 7440-42- 8 for boron

ANZG has developed a water quality guideline for boron (ANZG, 2021). Very high reliability default guideline values (DGVs) for (dissolved) boron in freshwater were derived from 22 chronic (long-term) toxicity data, comprising eight fish, two amphibians, three crustaceans,

one bivalve, three macrophytes, one green microalga, three diatoms and one blue–green alga. The DGVs for 99, 95, 90 and 80% species protection are 340 µg/L, 940 µg/L, 1,500 µg/L and 2,500 µg/L, respectively. The 95% species protection level for boron in freshwater (940 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems.

C. Terrestrial Toxicity

Relevant and reliable chronic no-effects values were identified for 39 terrestrial species or microbial processes. No-effect levels for dissolved boron ranged between 7.2 mg B/kg soil dw and 86.7 mg B/kg soil dw. The plant *Zea mays* was the most sensitive trophic level. The least sensitive species was the nematode *C.elegans*. A Species Sensitivity Distribution (SSD) has been developed for the assessment of boron in the terrestrial compartment, using the reliable species-specific chronic toxicity effect levels that have been generated in various research studies (ECHA) [KI Score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ulexite is a naturally-occurring mineral. For the purposes of this PBT assessment, the persistence criteria is not considered applicable to this inorganic substance.

Bioaccumulation is not applicable to naturally-occurring minerals, such as ulexite. Although boron is slowly released from ulexite, limited data indicate that bioaccumulation is not significant in aquatic and terrestrial food chains. Thus, it does not meet the criteria for bioaccumulation.

There are no aquatic toxicity studies on ulexite. The lowest chronic toxicity value for boron is > 0.1 mg/L. The acute E(L)C_{50} values for boron is > 1 mg/L. Thus, based on boron, ulexite does not meet the criteria for toxicity.

Therefore, ulexite is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

GHS07, GHS08

B. Labelling

Warning!

Danger!

According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child and causes serious eye irritation.

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Ulexite is non-flammable, combustible, or explosive. It is a flame retardant.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Ulexite is slightly water-soluble; at high concentrations it may cause damage to trees or vegetation by root absorption. Do not flush to drains.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ulexite.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Ulexite is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

American Borate Company. (2016). Technical specifications on Ulexite 45 micron ground. Available at: http://www.americanborate.com/media/19191/ulexite-1319-33-1-2016-technical-specification.pdf.

ANZG. (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Broschat, T.K. (2008). Release rates of soluble and controlled-release boron fertilizers. HorTechnology 18(3): 471-474.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Etimine USA, Inc. (2016). Safety Data Sheet on Ulexite. Available at: http://www.etimineusa.com/sites/etimineusa.com/files/SDS%20-%20Ulexite%202016%20-%202018_0.pdf

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Saiki, M.J., Jennings, M.R., and Brumbaugh, W.B. (1993). Boron, Molybdenum, and Selenium in aquatic food chains from the Lower San Joaquin River and its tributaries, California. Archives of Environmental Contamination and Toxiciology. 24, 307-319.

Thompson et al. (1976). Toxicity, uptake and survey studies of boron in the marine environment. Water Research Vol. 10. pp 869 to 875, 1976.

WHO. (1998). World Health Organisation, Environmental health criteria 204 – boron, viewed 26 August 2015. http://www.inchem.org/documents/ehc/ehc/ehc204.htm.

CRYSTALLINE SILICA, QUARTZ (CAS NO. 14808-60-7)
CRYSTALLINE SILICA, CRISTOBALITE (CAS NO. 14464-46-1)
CRYSTALLINE SILICA, TRIDYMITE (CAS NO. 15468-32-3)
NON-CRYSTALLINE SILICA (IMPURITY) (CAS NO. 7631-86-9)
DIATOMACEOUS EARTH (CAS NO. 61790-53-2)
DIATOMACEOUS EARTH, CALCINED (CAS NO. 91053-39-3)

This dossier on crystalline silica, quartz, cristobalite and tridymite; non-crystalline silica (impurity); diatomaceous earth; and diatomaceous earth, calcined presents the most critical studies pertinent to the risk assessment of these substances in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

For the purpose of this dossier, crystalline silica, quartz (CAS No. 14808-60-7) has been reviewed as representative of crystalline silica cristobalite and tridymite, and non-crystalline silica (impurity). Crystalline silica, quartz is also considered representative of diatomaceous earth and diatomaceous earth, calcined, as they both consist mainly of silicon dioxide.

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dioxosilane

CAS RN: 14808-60-7

Molecular formula: SiO_2

Molecular weight: 60.084 g/mol

Synonyms: Cristobalite, Dioxide, Silicon

SMILES: O=[Si]=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Silica is an off-white granule that occurs naturally in various crystalline and amorphous or other non-crystalline forms. Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. Other crystalline forms of silica include cristobalite, tripoli and tridymite. Particle size is a key determinate of silica toxicity, since toxicity is restricted to particles that are small enough to be deposited into the target regions of the respiratory tract (OECD, 2011).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. It is a stable solid under typical environmental conditions. It will not biodegrade, bioaccumulate, nor will it sorb to sediments or soils.

B. Biodegradation

No data are available. Based on the crystalline form of the substance, it is not expected to biodegrade.

C. Environmental Distribution

No experimental data are available for crystalline silica. As a stable inorganic solid, it is not soluble in water, and it will not sorb to soils or sediment.

D. Bioaccumulation

There are no bioaccumulation studies on crystalline silica.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Human exposure to crystalline silica via inhalation can lead to silicosis, lung cancer and pulmonary tuberculosis (WHO, 2000).

B. Acute Toxicity

No adequate acute oral, dermal or inhalation exposure studies are available for quartz, cristobalite or tridymite.

Most acute toxicity studies for quartz or cristobalite were conducted using intratracheal instillation. Intratracheal instillation is the introduction of the substance directly to the trachea and is used to test respiratory toxicity of a substance.

Single intratracheal instillation of quartz caused inflammatory effects and formation of discrete silicotic nodules in rats, mice and hamsters (IARC, 2012; WHO, 2000). Other effects like oxidative stress, cellular proliferation and increases in water, protein and phospholipid content of rat lungs, apoptosis (programmed cell death) and lung cancer were also noted.

In an acute dose study, rats were dosed once with 0, 0.75, 1.5, 3.0, 6.0 or 12 mg/kg bw/day quartz by intratracheal instillation (Seiler et al., 2001). The lowest observed adverse effect level (LOAEL) of 0.75 mg/kg bw/day was derived from these studies.

Two other similar studies of single intratracheal instillation of quartz reported higher LOAELs in rats (3 and 40 mg/kg bw/day) based on inflammation and fibrosis (Saffiotti et al., 1996).

C. Irritation

No data available.

D. Sensitisation

No data available.

E. Repeated Dose Toxicity

Oral

No data available.

Inhalation

Repeated inhalation exposure of crystalline is known to cause adverse effects (IARC, 2012). Silicosis has been identified as the main non-cancer effect of silica exposure, although available epidemiologic data as well as animal data provide evidence for several other effects associated with silica exposure, such as silicotuberculosis, enlargement of the heart (cor pulmonale), interference with the body's immune system and damage to the kidneys (Health Canada, 2013).

Dermal

No data available.

F. Genotoxicity

No data available.

G. Carcinogenicity

Oral

No data available.

Inhalation

The International Agency for Research on Cancer (IARC) has classified crystalline silica as a Group 1 carcinogen, as there was sufficient evidence for carcinogenicity in experimental animals and sufficient evidence for carcinogenicity of inhaled crystalline silica from occupational sources (IARC, 1997; IARC, 2012).

H. Reproductive Toxicity

No data available.

I. Developmental Toxicity

No data available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on crystalline silica is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Crystalline silica does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Although no data are available, crystalline silica is expected to exhibit low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

No aquatic toxicity data were available.

C. Terrestrial Toxicity

No terrestrial toxicity data were available.

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Crystalline silica is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to crystalline silica.

As an inorganic complex it is not expected to bioaccumulate. Thus, crystalline silica does not meet the screening criteria for bioaccumulation.

Crystalline silica is not expected to cause adverse effects in environmental receptors. Thus, this substance does not meet the screening criteria for toxicity.

Therefore, crystalline silica is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

H373 – may cause damage to organs through prolonged or repeated exposure.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention if symptoms persist.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Get medical attention if respiratory irritation develops or breathing becomes difficult.

Ingestion

Rinse mouth. Do not induce vomiting. Get medical attention if symptoms occur.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use extinguishing media appropriate for surrounding material.

Specific Exposure Hazards

Reacts with hydrofluoric acid (HF) forming toxic gas (SiF_4).

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Pick up mechanically – vacuum up. Avoid generating dust. If formation of dust cannot be avoided, use respiratory filter device. Dispose of the material collected according to regulations.

D. Storage And Handling

General Handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes, skin and clothing. Avoid dust formation. Do not breathe dust. Wash thoroughly after handling. Use with adequate ventilation.

Storage

Provide adequate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits. Keep containers tightly closed in a dry, cool, well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has established an occupational exposure standard for exposure to crystalline silica of an 8-hour time weighed average (TWA) exposure limit of 0.05 mg/m^3.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls

to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; as well as before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Crystalline silica is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Health Canada. (2013). Environment Canada, Health Canada. Screening Assessment for the Challenge: Quartz (CAS 14808-60-7) and Cristobalite (CAS 14464-46-1). June 2013. https://www.ec.gc.ca/ese-ees/1EB4F4EF-88EE-4679-9A6C-008F0CBC191C/FSAR_B12%20-%2014464-46-1%20%26%2014808-60-7%20%28QC%29_EN.pdf

IARC. (1997). Silica, some silicates, coal dust and Para-aramid fibrils. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 15-22 October 1996. IARC Monogr Eval Carcinog Risks Hum. 1997;68:1–475.

IARC. (2012). Silica dust, crystalline, in the form of quartz or cristobalite. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 17-24 March, 2009. IARC Monogr Eval Carcinog Risks Hum. 2012;100C:355–405

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2011). OECD -SIDS Initial Targeted Assessment Profile on Quartz and Cristobalite, SIAM 32, 19-21 April 2011. https://hpvchemicals.oecd.org/ui/handler.axd?id=b68bb357-e6dd-4db9-b05c-8148223fc0ff.

Saffiotti, U., Williams, O., Lambert, N., Daniel, N., Kaighn, M.E., Mao, Y., Shi, X. (1996). Carcinogenesis by crystalline silica: animal, cellular, and molecular studies. In:Castranova V, Vallyathan V, Wallace WE, eds. Silica and silica-induced lung diseases. Boca Raton, FL, CRC Press, pp. 345–381.

Seiler, F., Rehn, B. and Bruch, J. (2001). Evidence of a no-effect level in silica–induced rat lung mutagenicity but not in fibrogenicity. Archives of Toxicology 74: 716-719.

WHO. (2000). Concise International Chemical Assessment Document 24 - Crystalline Silica, Quartz. Produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals. WHO Geneva.

SODIUM CHLORIDE

This dossier on sodium chloride presents the most critical studies pertinent to the risk assessment of sodium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): sodium; chloride

CAS RN: 7647-14-5

Molecular formula: NaCl

Molecular weight: 58.44 g/mol

Synonyms: Halite, Salt, Table salt, Saline, Rock salt, Common salt, Dendritis, Purex'

SMILES: [Cl-].[Cl-].[Ca+2]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystaline solid	-	ECHA
Melting Point	801 °C @ 101.3 kPa	-	ECHA
Boiling Point	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Density	2163 kg/m^3 @ 20 °C	1	ECHA
Vapour Pressure	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Partition Coefficient (log K_{ow})	The study does not need to be conducted, because NaCl is inorganic.	1	ECHA
Water Solubility	317 g/L @ 20°C	2	ECHA
Dissociation Constant (pKa)	Not applicable, NaCl is an electrovalent substance.	-	ECHA

III. ENVIRONMENTAL FATE SUMMARY

Sodium chloride (NaCl) dissociates completely in aqueous solutions to sodium (Na^+) and chloride (Cl^-) ions. Sodium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of sodium (Na^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH, and organic matter. Similar to potassium, sodium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (DoEE, 2017; OECD, 2001).

Chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001). Neither sodium chloride nor its dissociated ions are expected to bioaccumulate.

Release to surface waters under the assessed circumstances is expected to have limited long-term environmental effects as these salts are ubiquitous and are present in most water, soil and sediment, therefore organisms are adapted to a level of exposure. The magnitude of the acute effect for a receiving aquatic environment would depend on the released concentrations as well as the degree of adaptation of species present to these naturally occurring ions and salts (DoEE, 2017).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Historically, sodium chloride (as a major ingredient in edible salt) has been commonly used in cooking as a condiment and food preservative. Sodium is an electrolyte that regulates the amount of water in your body and also plays a part in nerve impulses and muscle contractions. When depleted in the body, sodium must be replaced in order to maintain intracellular osmolarity, nerve condition, muscle contraction and normal renal function. Sodium chloride is used to treat or prevent sodium loss caused by dehydration, excessive sweating or other causes.

The NHMRC has established dietary guidelines for the intake of sodium per day (adult) as less than 2,000 mg sodium per day (NHMRC, 2007 updated 2017). Sodium chloride is categorised under GRAS (Generally Recognised as Safe) by the FDA (U.S. Food and Drug Administration) and the average daily levels of sodium intake for adults range from 2 to 5 grams. A technical report by WHO and the Food and Agriculture Organization (FAO) recommended the consumption of less than 5 grams sodium chloride (or 2 grams sodium) per day as a population nutrient intake goal, while ensuring that the salt is iodised (WHO, 2007).

NICNAS has assessed sodium chloride in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health or the environment[1] .

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 7647-14-5

Sodium chloride has low acute toxicity by the oral, dermal or inhalation route. It is not a skin irritant or a skin sensitiser. Long-term studies in rats fed sodium chloride showed elevated blood pressure. It is not a carcinogen and nor a developmental toxicant.

B. Acute Toxicity

Oral

The acute oral LD_{50} values of sodium chloride in rats is greater than 3,550 mg/kg with fiducial limits of 3,040 – 4,140 mg/kg (ECHA) [KI scores = 2].

Dermal

A dermal toxicity study was conducted in rabbits and the LD_{50} value was greater than 10,000 mg/kg and hence not classified according to EU Annex VI (ECHA) [KI scores = 2].

Inhalation

An acute inhalation toxicity study was conducted at a dose of 42 mg/L administered as an aerosol of a 20% aqueous solution to male rats and the results of the study indicated that the LC_{50} of sodium chloride was greater than 42 mg/L (42,000 mg/m^3) and hence not classified (ECHA) [KI scores = 2].

C. Irritation

Skin

When in contact with the intact skin, sodium chloride causes no response, either in undiluted form or in solution. Sodium chloride is considered to be slightly to not irritating to the skin (ECHA) [KI score = 2].

Eye

No adequate or reliable studies are available.

D. Sensitisation

Sodium chloride is not considered to be a skin sensitiser (ECHA).

E. Repeated Dose Toxicity

Oral

The estimated fatal dose of sodium chloride is approximately 0.75 to 3.00 g/kg (HSDB - Hazard Substance Data Bank - 750 to 3000 mg/kg). The lowest toxic dose (TDLo) for an adult man with normal blood pressure is 8,200 mg/kg (Patty's Handbook of Toxicology). High oral sodium chloride intake is associated with increased risk of hypertension; however, this is a well studied field in humans and additional animal testing data would not add value. Based on the studies, sodium chloride is not classified for any repeated dose effects.

A two-year feeding study was conducted to investigate the impact of sodium chloride on rats. Animals received a chronic administration at doses of 4% sodium chloride over a period

of 2 years which induces elevated blood pressure in the rats. The LOAEL from this key study identified a dose level of < 4% via the diet and the calculated LOAEL was 2,533 mg/kg/day (ECHA).

Dermal

No adequate or reliable studies are available.

Inhalation

No adequate or reliable studies are available.

F. Genotoxicity

No adequate or reliable studies are available.

G. Carcinogenicity

Sodium chloride is not classified as a carcinogen (ECHA). Sodium chloride is not listed with IARC.

H. Reproductive Toxicity

No adequate or reliable studies are available.

I. Developmental Toxicity

Sodium chloride is not classified as a developmental toxicant (ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2011).

The Australian drinking water guideline value for sodium ions is 180 mg/L based on aesthetics (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Sodium chloride is of low acute toxicity concern to aquatic organisms, in part because of the effect of pH changes from the dissociated hydrogen ion.

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} value of 5,840 mg/L for sodium chloride was determined in a continuous flow-through exposure system with bluegill sunfish (*Lepomis macrochirus*) (ECHA) [KI score =1].

The EC_{50} 48-hour (immobilisation, *Daphnia magna*) was determined to be 1,900 mg/L (ECHA) [KI score = 2].

The EC_{50} of NaCl at 96 hours to *Lemna* was determined for comparison and found to be 6,870 mg/L (6.87 g/L) (ECHA) [KI score = 1].

Chronic Studies

The 33-day NOEC value of 252 mg/L for sodium chloride was determined in a continuous flow-through exposure system with early life stage fathead minnows (*Pimephales promelas*) (ECHA) [KI score = 2].

A 21-day NOEC (reproduction, *Daphnia pulex*) was determined to be 314 mg/L (ECHA) [KI score = 2].

C. Terrestrial Toxicity

The mean 14-day LC_{50} for three experiments conducted with the earthworm, *E. fetida* was 3,296 mg NaCl/kg soil dw. The 10-week NOEC (based on mortality) was 3,507 mg NaCl/kg soil for the earthworm, *E. fetida* (ECHA) [KI score = 2].

In a 7-day exposure study with red fescue grass, the EC_{50} for germination was 500.8 mg NaCl/kg soil dw. In a 7-day exposure study with Kentucky bluegrass, the NOEC for stem growth was 243 mg NaCl/kg soil dw (ECHA) [KI score = 2].

The 12-hour LD_{50} for wild house sparrows was approximately 3,000 - 3,500 mg/kg NaCl (ECHA) [KI score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium chloride is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium chloride.

Bioaccumulation in fish is not expected given the inorganic nature of the substance. Thus, sodium chloride does not meet the screening criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on sodium chloride are greater than 0.1 mg/L. The E(L)C_{50} values from the acute aquatic toxicity studies on sodium chloride are > 1 mg/L. Thus, sodium chloride, does not meet the criteria for toxicity.

The overall conclusion is that sodium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes of chloride and sodium oxide (above 1,413°C). Depending on conditions, decomposition products may include hydrogen chloride gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment and Energy [DoEE]. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report prepared by the Chemicals and Biotechnology Assessments Section (CBAS), in the Chemicals and Waste Branch of the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HSBD. Hazardous Substances Data Bank. https://pubchem.ncbi.nlm.nih.gov/source/hsdb/6368

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NHMRC. (2007). Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes, Version 1.2 updated September 2017. National Health and Medical Research Council. Department of Health and Ageing. Australian Government.

OECD. (2001). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

Patty's Toxicology, 6 Volume Set, 6th Edition. Volume 3: 375. July 2012.

WHO. (2007) Reducing salt intake in populations: report of a WHO forum and technical meeting. https://www.who.int/dietphysicalactivity/Salt_Report_VC_april07.pdf. Accessed 28 Apr 2020

Appendix C.2 May 2021 Risk Dossiers

BORIC ACID (CAS NO. 10043-35-3)
SODIUM TETRABORATE DECAHYDRATE (BORAX) (CAS NO. 1303-96-4)

This dossier presents the most critical studies pertinent to the risk assessment of two boron compounds (boric acid and borax) in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): boric acid

CAS RN: 10043-35-3

Molecular formula: BH_3O_3

Molecular weight: 61.84 g/mol

Synonyms: orthoboric acid; boracic acid; borofax; boron hydroxide; boron trihydroxide

SMILES: B(O)(O)O

Chemical Name (IUPAC): disodium bicyclo[3.3.1]tetraboroxane-3,7-bis(olate)

CAS RN: 1303-96-4

Molecular formula: $B_4Na_2O_7$

Molecular weight: 381.4 g/mol

Synonyms: sodium tetraborate decahydrate; borax; monosodium metaborate; sodium borate; sodium borate (NaBO2); sodium diborate; sodium meta borate; sodium metaborate; sodium tetraborate

SMILES: B1(OB2OB(OB(O1)O2)[O-])[O-].O.O.O.O.O.O.O.O.O.O.[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Limited measured data are available for borax. In the environment, borax is expected to dissociate and/or hydrolyse to release boric acid at neutral pH. Therefore, measured data available for boric acid have been presented as analogue data for this substance.

Key physical and chemical properties for boric acid are shown in Table 1.

Table 1: Overview of the Physico-chemical Properties of Boric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odourless, crystalline solid	2	ECHA
Melting Point	> 100°C (decomposes)	1	ECHA
Boiling Point	Not Applicable	-	ECHA
Density	1,489 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure	0 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	Not Applicable, substance is inorganic	-	ECHA
Water Solubility	48.8 g/L @ 20°C	1	ECHA
Dissociation Constant (pKa)	8.94 @ 20°C	1	ECHA

Boron is almost exclusively found in the environment in the form of boron-oxygen (B-O) compounds, which are often referred to as borates. The high strength of the B-O bond relative to those between boron and other elements makes boron oxide compounds stable compared to nearly all non-oxide boron materials. Indeed, the B-O bond is among the strongest found in the chemistry of naturally occurring inorganic substances (ECHA).

In the environment, borates and compounds of boric acid will dissociate and/or hydrolyse to form the same boron species. For example, when borax dissolves in dilute solutions, it dissociates into Na^+ ions and the tetraborate anion ($B_4O_5(OH)_4^{2-}$). Boric acid ($B(OH)_3$) is formed following acid catalysed hydrolysis of the tetraborate anion. Under alkaline conditions, dilute solutions of the tetraborate anion depolymerise rapidly to the mononuclear borate anion ($B(OH)_4^-$) (NICNAS, 2019).

Boric acid is a Lewis acid that acts as a weak monoprotic acid by accepting OH^- and not as a proton donor (pKa 9.14). Therefore, at the near neutral pH of most environmental systems and at low concentrations (< 0.025 mol B/L), the neutral mononuclear species ($B(OH)_3$) will dominate and only a small proportion of boron will exist as the borate monoanion, $B(OH)_4^-$. Therefore, in the environment boric acid is in equilibrium with borate anions. Both species are very stable as they do not undergo biotransformation or redox reactions under normal environmental conditions (NICNAS, 2019).

Exposure to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. The B equivalents used are a generic designation rather than a designation of the element boron. The factor for converting boric acid to B-equivalents is 0.1748. The factor for converting borax to B-equivalents is 0.2149.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Borax will transform into boric acid in the aquatic environment. In the environment boric acid is in equilibrium with borate anions. Degradation is not applicable to inorganic borates.

Boric acid is highly soluble in water. Some partitioning to soil and sediment does occur, but this adsorption is pH dependent. It has a low potential for bioaccumulation.

B. Partitioning

Borax will transform into boric acid in the aquatic environment. In the environment boric acid is in equilibrium with borate anions. Both species are very stable as they do not undergo biotransformation or redox reactions under normal environmental conditions. Boric acid is highly water soluble and it tends to remain in surface waters. Although some partitioning from water to soil and sediment does occur, the adsorption is pH dependent with the greatest adsorption occurring under alkaline conditions (pH 7.5 to 9.0) (NICNAS, 2019).

C. Biodegradation

Degradation is not applicable to inorganic borates. It is not subject to hydrolysis, photodegradation or biodegradation (ECHA). Inorganic borates are subject to chemical transformation processes (adsorption, complexation, precipitation, fixation) once released into the environment (ECHA).

D. Environmental Distribution

The Kp value for boron compounds was calculated as the median of all measured Kp values from the GEMAS project (Geochemical Mapping of Agricultural and Grazing Land Soil project): 2.19 L/kg dry weight (ECHA) [KI score = 2]. The chemistry of boron in soils and aquatic systems is simplified by the absence of oxidation-reduction reactions or volatilisation. Redox processes can mobilise Fe oxides and Mn oxides, which may lead to a release of boron in aquatic systems. Generally, sediments are characterised with higher pH values than the soil matrix, which increases the boron sorption capacity (ECHA).

If released to soil, based on this low Kp value, low vapour pressure and high water solubility, boric acid and borax are considered relatively mobile in the environment, under certain conditions (ECHA).

E. Bioaccumulation

The WHO review of boron (WHO, 1998) noted that “highly water soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as un-dissociated and highly soluble boric acid at neutral pH”. BCFs of < 0.1 to 10.5 L/kg have been reported from laboratory tests of fish and oysters (Hamilton and Wiedmeyer, 1990; Thompson et al., 1976).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Borax exhibits low acute toxicity by the oral and dermal routes. Boric acid exhibits low acute toxicity by the oral, dermal and inhalation routes. Neither substance is a skin or eye irritant, nor a skin sensitiser. In aqueous media at physiological pH, borax will predominantly exist as un-dissociated boric acid. The developing foetus and the testes are the two most sensitive targets of boron toxicity in multiple species. The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic

epithelium, impaired spermatogenesis, reduced fertility and sterility. The developmental effects from boron exposure include high prenatal mortality, reduced foetal body weight, malformations and variations. Repeated inhalation exposure to read-across substance boron oxide resulted in slight irritation to the respiratory tract, but no systemic toxicity. Boric acid was not genotoxic, and boric acid and borax was not carcinogenic to rodents.

B. Toxicokinetics

Boric acid is not metabolised in either animals or humans, owing to the high energy level required (523 kJ/mol) to break the B-O bond. Other inorganic borates convert to boric acid at physiological pH in the aqueous layer overlying the mucosal surfaces prior to absorption. Most of the simple inorganic borates exist predominantly as undissociated boric acid in dilute aqueous solution at physiological and environmental pH, leading to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under the same conditions. Additional support for this derives from studies in which more than 90% of administered doses of inorganic borates are excreted in the urine as boric acid. Absorption of borates via the oral route is nearly 100%. For the inhalation route also, 100% absorption is assumed as worst-case scenario. Dermal absorption through intact skin is very low with a percent dose absorbed of 0.226 ± 0.125 in humans. Using the % dose absorbed plus standard deviation (SD) for boric acid, a dermal absorption for borates of 0.5% (rounded from 0.45%) can be assumed as a worse-case estimate (ECHA).

In the blood boric acid is the main species present and is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2 to 3 times higher than in other tissues. Boric acid is excreted rapidly, with elimination half-lives of 1 hour in the mouse, 3 hours in the rat and < 27.8 hours in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine (ECHA).

C. Acute Toxicity

The oral LD_{50} of borax in rats is > 2,500 mg/kg (ECHA) [KI score = 1]. The oral LD_{50} of boric acid in rats is 3,450 mg/kg (ECHA) [KI score = 1].

There are no acute inhalation studies on borax. In a read-across study for borax, the 4-hour inhalation LC_{50} value for disodium tetraborate pentahydrate in rats is > 2.04 mg/L (ECHA) [KI score = 1]. The 4-hour inhalation LC_{50} value for boric acid in rats is > 2.01 mg/L. The mass median aerodynamic diameter (MMAD) was 2.8 µm (ECHA) [KI score = 1]. In another study, the 4-hour inhalation LC_{50} value for boric acid in rats was > 2.03 mg/L (ECHA) [KI score = 1].

The dermal LD_{50} of borax in rabbits is > 2,000 mg/kg (ECHA) [KI score = 2]. The dermal LD_{50} of boric acid in rabbits is > 2,000 mg/kg (ECHA) [KI score = 1].

D. Irritation

Application of 0.5 g of borax to the skin of rabbits for 4 hours under occlusive conditions was not irritating. The mean erythema and oedema scores were 0.00 (ECHA) [KI scores = 2]. Application of 0.5 g. of boric acid to the skin of rabbits for 24 hours under occlusive conditions was not irritating. The mean of the 24 and 72-hour scores were 0.13 for erythema and 0.00 for oedema (ECHA) [KI scores = 1].

Disodium tetraborates are eye irritants. Instillation of 0.08 mL of read-across substance disodium tetraborate pentahydrate into the eyes of rabbits was slightly irritating. The mean of 24, 48, and 72 hours scores were 0.22 for corneal opacity; 0.22 for iridial lesions; 2.8 for conjunctival redness; and 1.89 for chemosis. The effects were fully reversible (ECHA) [Kl score = 1].

Boric acid induced mild conjunctivae redness and chemosis and minor effects on the iris. The effects were reversible within 7 days (ECHA). Instillation of 100 mg of boric acid into the eyes of rabbits was slightly irritating. The mean of 24, 48, and 72-hour scores were 0.00 for corneal opacity; 0.11 for iridial lesions; 0.94 for conjunctival redness; and 0.56 for chemosis (ECHA) [Kl score = 1].

E. Sensitisation

There are no skin sensitisation studies on Borax. Read-across substances disodium tetraborate pentahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1].

Boric acid was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1]. Sodium tetraborate pentahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1]. Sodium tetraborate decahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1].

F. Repeated Dose Toxicity

<u>Oral</u>

Male and female SD rats were given in their feed boric acid at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg/day, respectively (USEPA, 2004). By week 6, all animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen ovary and adrenal weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes and adrenal weights. The adrenals of 4 of the 1,750 ppm males showed minor increases in lipid content and size of the cells in the zona reticularis. Atrophied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. One 525 ppm male had partial testicular atrophy. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

Male and female SD rats were given in their diet borax at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg/day, respectively (USEPA, 2004). By week 6, all the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen and ovary weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes and brain weights. The adrenals of the majority of the 1,750 ppm males and females showed slight to moderate increases in lipid content and size of the cells in the zona reticularis. Atrophied testis (complete atrophy of the spermatogenic epithelium

and decreased in the size of the seminiferous tubules) was seen in all the 1,750 ppm males. Four 525 ppm males had partial testicular atrophy. Spermatogenic arrest was found in one 525 ppm male. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg/day (Weir and Fisher, 1972) [KI score = 2].

Male and female B6CF1$_1$ mice were given in the diet 0, 1,200, 2,500, 5,000, 10,000 or 20,000 ppm boric acid for 13 weeks (control and highest dose group) or 16 weeks (remaining dose groups). These dietary levels correspond to approximately 0, 34, 70, 141, 281 and 563 mg B/kg/day for males, respectively: and 0, 47, 97, 194, 388 and 776 mg B/kg/day for females, respectively (USEPA, 2004). There was mortality (8/10 males; 6/10 females) in the 20,000 ppm group, as well as hyperkeratosis and acanthosis. One male also died in 10,000 ppm group. Degeneration or atrophy of the seminiferous tubules occurred in the ≥ 5,000 ppm males. Minimal to mild extramedullary haematopoiesis of the spleen was observed in all dose groups. The LOAEL for this study is 1,200 ppm, corresponding to 34 and 47 mg B/kg/day for males and females, respectively (NTP, 1987) [KI score = 2].

Male and female SD rats were given in their diet 0, 117, 350 or 1,170 ppm boric acid for two years. The average intake has been estimated to be approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively (USEPA, 2004). The 1,170 ppm rats had decreased food consumption during the first 13 weeks of the study and suppressed growth throughout the study. Signs of toxicity in the 1,170 ppm animals included swelling and desquamation of the paws, scaly tails, inflammation of the eyelids and bloody discharge from the eyes. All the 1,170 ppm males had testicular atrophy at the 6, 12 and 24-month time points. The seminiferous epithelium was atrophied, and the tubular size in the testes was decreased. There were significant decreases in the absolute and relative testes weights. Brain and relative thyroid weights were increased. The NOAEL for this study is 350 ppm B equivalents or 17.5 mg B/kg/day (Weir and Fisher, 1972) [KI score = 2].

Male and female B6C3F$_1$ mice were given up to 20,000 ppm boric acid in their feed for 13 weeks (NTP, 1987). Eight out of the 10 males and 6 out of the 10 females from the 20,000 ppm group died and 1 of the 10 males from the 10,000 ppm group died before the end of the study. Symptoms included nervousness, haunched appearance, dehydration, foot lesions and scaly tails. Incidences of extra medullary haematopoiesis of the spleen were observed of varying severity in all dose groups for both males and females and hyperkeratosis and/or acanthosis of the stomach observed at the highest dose only in both males and females. At doses > 5,000 ppm (142 mg B/kg bw for the male), degeneration or atrophy of the seminiferous tubules was observed. The NOAEL for this study is 34 mg B/kg/day (NTP, 1987) [KI score = 2].

Inhalation

Male and female rats were exposed by inhalation to 0, 77, 175 or 470 mg/m^3 boron oxide. The exposures were 6 hours/day, 5 days/week for 24, 12, and 10 weeks for the 77, 175, and 470 mg/m^3 concentrations groups, respectively. The MMAD were 2.5, 1.9 and 2.4 µm for the 77, 175 and 479 mg/m^3 concentrations groups, respectively. There was no evidence of systemic toxicity. Some of the 470 mg/m^3 had reddish exudate from the nose. As these animals were covered with dust, this effect may have been local irritation of the nose and from the animals scratching the nose. The NOAEL for systemic toxicity is 470 mg/m^3, the highest exposure concentration tested. The NOAEL for localised effects (irritation) is 175 mg/m^3 (ECHA) [KI score = 2].

Dermal

No studies are available.

G. Genotoxicity

In Vitro Studies

There are no *in vitro* genotoxicity studies on borax. Table 2 presents the results of the *in vitro* genotoxicity studies on boric acid.

Table 2: *In vitro* Genotoxicity Studies on Boric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations (Human peripheral lymphocytes)	NS	+	2	ECHA
Unscheduled DNA synthesis (rat liver cells)	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable; NS, not specified.

In Vivo Studies

No studies are available on borax.

Male and female Swiss Webster mice were given two daily doses of 0, 225, 450, 900, 1,800 or 3,500 mg/kg boric acid. The frequency of micronucleated polychromatic erythrocytes were not increased at any dose level (ECHA) [KI score = 1].

H. Carcinogenicity

Oral

Male and female SD rats were given in their diet disodium tetraborate decahydrate (Borax) or boric acid at doses of 0, 117, 350 or 1,170 ppm as B equivalents (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day) for two years. There was no mention of tumours in the report. Nevertheless, NTP (1987) concluded that this study provided adequate data on the lack of carcinogenic effects of boric acid in rats (Weir and Fisher, 1972; USEPA, 2004).

Male and female B6C3F_1 mice were given in their diet 0, 2,500 or 5,000 ppm boric acid for 103 weeks. The dietary levels are equivalent to 0, 446 or 1,150 mg/kg/day boric acid or 0,

78.1 or 201.3 mg B/kg/day. There was no evidence of carcinogenicity (NTP, 1987) [Kl score = 2].

I. Reproductive Toxicity

A three-generation reproductive toxicity study was conducted in Sprague-Dawley rats with boric acid. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation and appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170-ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

A three-generation reproductive toxicity study was conducted in Sprague-Dawley rats with borax. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170-ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

In a continuous breeding protocol, male and female CD-1 mice were given in their diet 0, 1,000, 4,500 or 9,000 ppm boric acid in their feed. The authors estimated that the average daily intakes were 0, 26.6, 111 and 220 mg B/kg/day to males; and 0, 31.8, 152 and 257 mg B/kg/day to females. Boric acid consumption did not differ among the groups. There were no litters in the 9,000 ppm breeding pairs. At 4,500 ppm, there was a successful first litter, after which there was a progressive decrease in fertility; only one pair produced a fourth and fifth litter. All fertility indices were affected in the 4,500 ppm group. A complete crossover mating trial was conducted using control mice and the 4,500 ppm mice. The results showed that the probable cause of the reduced fertility was a decrement in male fertility. A dose-related decrease in body, testicular and epididymal weights was observed in the 4,500 and 9,000 ppm F_0 males. Sperm count was significantly decreased in these two dose groups, and percent motile sperm was decreased in all dose groups. Testicular histopathology showed seminiferous tubular atrophy in the 9,000 ppm males and partial atrophy of the seminiferous tubules in the 4,500 ppm males. There were no histopathologic changes in the 4,500 ppm females. No statistically significant decreases in mating index, fertility index or live pups/litter in the 4,500 ppm females, but the number of days to litter in this dose group was increased. Oestrous cyclicity was unaffected. Reproductive organ weights were unaffected, but relative maternal liver and kidney/adrenal weights were reduced. An F_1 fertility trial was performed using offspring from the 1,000 ppm groups. There were no decreases in mating, fertility or reproductive performance. The F_2 adjusted live pup weight was slightly, but significantly, reduced from controls. A clear NOAEL for reproductive toxicity in males was not seen in this study. The 1,000 ppm males had decreased sperm motility in

the F_0 generation and decreased sperm concentration in the F_1 generation. Decreased F_2 pup relative body weight was statistically significant from controls. The NOAEL in this study for females is 1,000 ppm boric acid or 32 mg B/kg/day). The LOAEL in this study for males is 1,000 ppm or 27 mg B/kg/day; a NOAEL was not established (Fail et al*.,* 1991) [Kl score = 2].

J. Developmental Toxicity

No studies are available on borax.

Pregnant female SD rats were given 0, 0.1, 0.2 or 0.4% boric acid in their feed on gestational days (GD) 0 to 20 or 0.8% boric acid on GD 6 to 15. The average amounts of boric acid ingested were estimated to be 0, 78, 163, 330 or 539 mg/kg/day (0, 13.6, 28.5 or 57.7 mg B/kg/day), respectively. Effects on the pregnant rats were altered food and/or water intake at ≥ 0.2% boric acid, increased liver and kidney weights relative to body weights at ≥ 0.2%, reduced weight gain at ≥ 0.4%, and increased corrected weight gain at 0.4% boric acid. There was a reduction in foetal body weights in all treated groups (94, 87, 63 and 47% of control weight, respectively). Increased malformations occurred at ≥ 0.2%, and prenatal mortality was increased at 0.8%. There was a dose-response for altered skeletal morphology in rats (≥ 0.1%), and specific findings were significantly elevated above controls at ≥ 0.2%. Specifically, there was an increased incidence of short rib XIII (a malformation) and a decreased incidence or rudimentary or full rib(s) at lumbar I (an anatomical variation) (Heindel et al., 1992) [Kl score = 2].

Pregnant female SD rats were given in their feed 0, 0.025, 0.005, 0.075, 0.1 or 0.2% boric acid on GD 0 to 20. Approximately half of the dams were terminated on GD 20, and the remaining dams delivered their litters. Pup growth and viability were monitored until postnatal day (PND) 21. The average amounts of boron ingested on GD 20 were: 0, 3.3, 6.3, 9.6, 13.3 and 25 mg B/kg/day, respectively. The average amounts of boron ingested on PND 21 were 0, 3.2, 6.5, 9.7, 12.9 and 25.3 mg B/kg/day, respectively. There were no maternal deaths and no treatment-related clinical signs. Maternal body weights were similar across all groups during gestation. However, decreased maternal body weights (GD 19 and 20 at sacrifice) and decreased maternal body weight gain (GD 15-18 and GD 0-20) were statistically significant in trend tests. There was a 10% reduction in gravid uterine weight (statistically significant) in the 0.2% group. Corrected maternal weight (maternal gestational weight minus reduced gravid uterine weight) was unaffected by treatment. Feed intake in the 1,000 ppm dams was minimally affected and only during the first three days of dosing. Water consumption was higher in the treated groups after GD 15. The number of corpora lutea and uterine implantation sites, and the percentage of preimplantation loss were similar across all groups. Increased relative kidney weights were increased in the 0.2% group. There were no differences in the viability of the offspring between treated and controls. On GD 20, foetal body weight was 94% and 88% of controls in the 0.1% and 0.2% groups, respectively; recovery was complete at birth (~GD 22). The incidence of short rib XIII was increased on GD 20 in the ≥ 0.1% groups, but only in the 0.2% group at PND 21. The incidence of wavy rib was increased on GD 20 in the ≥ 0.1% group; the reversibility of this effect was confirmed on PND 21. There was a slight decrease in extra lumbar ribs in the 0.2% group on GD 20, and extra lumbar ribs were seen in the 0.2% group on PND 21. The developmental NOAEL was considered to be 0.075% boric acid or 9.6 mg B/kg/day on GD 20; and 0.1% boric acid or 12.9 mg B/kg/day on PND 21 (Price et al., 1996a) [Kl score = 1].

Pregnant Swiss mice were given in their diet 0, 0.1, 0.2 or 0.4% boric acid on gestational days (GD) 0 to 17. The average amounts of boric acid ingested were estimated to be 248, 452 or

1,003 mg/kg/day (0, 43.4, 79.0 or 175.3 mg/B/kg/day), respectively. Maternal toxicity consisted of mild kidney lesions (≥ 0.1%), increased water intake and relative kidney weights (0.4%), and decreased water intake during treatment. Foetal body weights were reduced in the ≥ 0.2% groups, and there were increased incidences of resorptions and malformed foetuses per litter in the 0.4% group. The LOAEL for maternal toxicity is 248 mg/kg/day boric acid or 43.4 mg B/kg/day; a NOAEL was not established. The NOAEL for developmental toxicity is 248 mg/kg/day boric acid or 43.4 mg B/kg/day (Heindel et al., 1992) [KI score = 2].

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 62.5, 125 or 250 mg/kg boric acid (0, 10.9, 21.9 or 43.7 mg B/kg) during GD 6-19. Feed intake was in the 250 mg/kg maternal animals during the exposure period, but it was increased in the ≥ 125 mg/kg dose groups. In the 250 mg/kg group, maternal body weights during GD 9-30, weight gain during GD 6-19, gravid uterine weight and number of corpora lutea per dam were significantly reduced. In the ≥ 125 mg/kg groups, maternal corrected gestational weight gain was increased compared to controls. Maternal liver weights were unaffected by treatment. In the 250 mg/kg group, relative, but not absolute, kidney weights were increased, although no effects in the kidney were noted in the histopathological examination. Prenatal mortality was increased in the 250 mg/kg group (90% resorptions/litter versus 6% for controls); the proportion of pregnant females with no live foetuses was increased (73% versus 0%), and live litter size was reduced (2.3 foetuses versus 8.8). Thus, there were only 14 live foetuses (6 live litters) available for evaluation in the 250 mg/kg group. The percentage malformed foetuses/litter was increased in the 250 mg/kg group, primarily due to cardiovascular defects (72% versus 3% of controls). There was no definitive maternal or developmental toxicity in the 62.5 or 125 mg/kg dose groups. The NOAEL for maternal and developmental toxicity is 125 mg/kg/day boric acid or 21.9 mg B/kg/day (Price et al., 1996b) [KI score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for boric acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021)).

A. Non-Cancer

An oral reference dose was not derived for boric acid or borax.

The Australian drinking water guideline value for boron (4 mg/L) may be applicable (ADWG 2011 updated 2021). The health-based ADWG value was based on a tolerable daily intake (TDI) of 0.16 mg/kg bw. This TDI is based on the NOAEL of 9.6 mg/kg/bw/day for foetal bodyweight effects in a rat developmental study (Price et al., 1996a) with an uncertainty factor of 60 (10 for interspecies and 6 for human intraspecies).

B. Cancer

There was no evidence of carcinogenicity in rat and mouse chronic studies conducted on borax and/or boric acid. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Borax and boric acid do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Borax and boric acid have low acute and chronic toxicity to aquatic organisms.

B. Aquatic Toxicity

In ecotoxicological tests for boron, the exposure concentrations are expressed as boron equivalents, i.e., mg B/L. This is because boric acid and borate salts will have the same boron speciation when dissolved in environmental matrices. Therefore, in the following sections toxicological values are given as mg B/L regardless of the form of boron that was tested.

Acute Studies

Borax will transform into boric acid in the aquatic environment. Table 3 lists the results of acute aquatic toxicity studies conducted on boric acid.

Table 3: Acute Aquatic Toxicity Studies on Boric Acid

Test Species	Endpoint	Results (mg B/L)	Klimisch score	Reference
Fathead minnow	96-hour LC_{50}	79.7	2	ECHA
Legumia recta (Black sandshell mussel)	96-hour LC_{50}	147	2	ECHA
Hyalella azteca	96-hour LC_{50}	64	2	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	52.4 mg B/L	1	ECHA

Chronic Studies

Long-term effects (LC_{10}) on freshwater fish ranged from 3.5 to 47 mg B/L. Adequate long-term LC_{10} of 21.6 mg B/L was found for the freshwater fish *P. promelas* in a study according to USEPA OPPTS 850.1400 (ECHA) [Kl score = 2].

Long-term effects (LC_{10}/NOEC) on reproduction on freshwater vertebrates ranged from 6.6 to 32 mg B/L based on several well-accepted guideline studies (ECHA) [Kl scores =1 or 2].

Boric acid has been evaluated for its toxicity towards the freshwater alga *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in an Alga growth inhibition test according to OECD 201 under GLP requirements. The exposure duration was 72 hours under static conditions. The NOEC growth rate determined from the study was 17.5 mg B/L (ECHA) [Kl score = 1].

The ANZG water quality guideline (2021) derived a very high reliability default guideline value (DGVs) for (dissolved) boron in freshwater from 22 chronic (long-term) toxicity data, comprising eight fish, two amphibians, three crustaceans, one bivalve, three macrophytes, one green microalga, three diatoms and one blue–green alga. The summary of representative data used by ANZG to develop a water quality guideline for boron is presented in Table 4. These values are noted to be consistent with those reported in ECHA. Additional chronic aquatic toxicity data is found in the ANZG Technical Brief (ANZG, 2021).

Table 4: Chronic Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg B/L)
Danio rerio	34-day NOEC (Biomass)	1.8
*Pimephales promela*s	32-day NOEC (Mortality)	11
Daphnia magna	14-day NOEC (Reproduction)	2.4
Pseudokirchneriella subcapitata	4-day NOEC (Growth)	2.8

1 - The DGVs are based on toxicity data for boron as either boric acid, H_3BO_3 (CAS 10043-35-3), or borax, $Na_2B_4O_710H_2O$ (CAS 1303-96-4), in freshwater.

In the chronic toxicity data set, fish sensitivity to boron ranged from the least sensitive species in the dataset (*Melanotaenia splendida*, LC_{10} 102 mg/L) to the third most sensitive species in the dataset (*Danio rerio*, NOEC 1.8 mg/L). Of the crustaceans, *D. magna* was best represented in the literature, with 18 published NOEC values (ranging from 2.4 mg/L to 29 mg/L) for six different endpoints from six different publications. The final NOEC of 2.4 mg/L used in the DGV derivation was lower than that for *C. dubia* (NOEC 5.6 mg/L) and for the amphipod *H. azteca* (NOEC 6.6 mg/L). For *P. subcapitata*, there were three separate studies available with toxicity data for boron. The toxicity values from these studies ranged from a NOEC of 2.8 mg/L to a NEC of 27 mg/L, varying with endpoint, duration and test medium used. Boron was least toxic to *P. subcapitata* when tested in algal growth medium with added $NaHCO_3$, suggesting that carbonate addition may have influenced boron toxicity. Therefore, although NECs are preferred to NOECs or EC10s, in this instance, a reliable NOEC of 2.8 mg/L was the most sensitive toxicity value for *P. subcapitata* (ANZG, 2021).

C. Sediment Toxicity

Limited sediment toxicity data are available for boric acid and boron containing compounds in general (NICNAS, 2019).

Chronic toxicity values for the effects of boric acid on sediment-dwelling invertebrates have been obtained for a freshwater midge (*Chironomus riparius*, harlequin fly), a freshwater bivalve (*Lampsilis siliquoidea*, fatmucket clam) and the aquatic worm (*Lumbriculus variegatus,* California blackworm). The respective toxicity values for these species are as follows: 28-day NOEC = 37.8 mg B/kg; 21-day LC_{25} (survival) = 363.1 mg B/kg; and 28-day NOEC = 100.8 mg B/kg (NICNAS, 2019).

Due to the high water solubility of boron and its low partitioning to sediment, sediment toxicity testing for boron is particularly challenging as it is difficult to ensure that exposure is through the solid phase (i.e., sediment) and not from the aqueous boric acid in the overlying water (NICNAS, 2019).

D. Terrestrial Toxicity

Ecotoxicological tests with plants and soil invertebrates have recorded modest chronic toxicity values (NOECs/ECs) in the range of 15.3 to 84.0 and 5.2 to 315 mg total B/kg, respectively (ECHA, 2008). However, to predict the potential toxicity of boron to plants and soil organisms, measuring the total boron concentration may be unsuitable. Instead, potential toxicity is better predicted using boron concentrations in the soil solution (extractable boron) (Mertens et al., 2011). In Australia, it is generally accepted that boron toxicity will pose a risk to terrestrial plants when soil concentrations exceed 15 mg/kg of extractable boron (NICNAS, 2019).

E. Calculation of PNEC

PNEC water

The ANZG water quality guideline (2021) derived a very high reliability DGV for (dissolved) boron in freshwater. The DGVs for 99, 95, 90 and 80% species protection are 340 µg/L, 940 µg/L, 1,500 µg/L and 2,500 µg/L, respectively. The 95% species protection level for boron in freshwater (940 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems (ANZG, 2021).

PNEC sediment

Limited sediment toxicity data are available for boric acid and boron containing compounds in general (NICNAS, 2019). Due to the high water solubility of boron and its low partitioning to sediment, sediment toxicity testing for boron is particularly challenging as it is difficult to ensure that exposure is through the solid phase (i.e., sediment) and not from the aqueous boric acid in the overlying water (NICNAS, 2019). K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as boric acid and borax. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. As a result, the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

In the ECHA REACH database (ECHA), a $PNEC_{soil}$ was derived for boron using the species sensitivity distribution method and an assessment factor of 2. The $PNEC_{soil}$ was determined to be 5.7 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Borax is an inorganic compound that dissociates completely to boric acid and the borate anion in aqueous media. Biodegradation is not applicable to these inorganic compounds; both boric acid and borate are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable.

A BCF of < 0.1-10.5 L/kg has been reported for borates in fish and oysters. This data suggests that boric acid does not bioaccumulate in the aquatic environment. Thus, boric acid and borax do not meet the criteria for bioaccumulation.

The chronic toxicity data on boric acid has a NOEC > 0.1 mg/L. Acute E(L)C_{50} values are > 1 mg/L. Thus, borax and boric acid do not meet the criteria for toxicity.

The overall conclusion is that borax and boric acid are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Inhalation]

Eye Damage Category 1

Reproductive Toxicant Category 1B

STOT SE Category 3 [Respiratory irritation]

In addition to the hazard statements corresponding the GHS classifications, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child, causes serious eye damage, is harmful if swallowed, is harmful if inhaled, is suspected of damaging fertility or the unborn child, may cause respiratory irritation and causes skin irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water. Do not induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

None identified.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage and Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for sodium perborate tetrahydrate.

Engineering Controls

Ensure adequate ventilation. Localised ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment

Respiratory Protection: Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium tetraborate decahydrate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZG. (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fail, P.A., George, J.D., Seely, J.C., Grizzle, T.B., and Heindel, J.J. (1991). Reproductive toxicity of boric acid in Swiss (CD-1) mice: assessment using the continuous breeding protocol. Fundam. Appl. Toxicol. 17: 225-239.

Hamilton, S.J., and Wiedmeyer, R.H. (1990). Concentrations of boron, molybdenum and selenium in chinook salmon. Trans. Amer. Fisheries Soc. 119: 500-510.

Heindel, J.J., Price, C.J., Field, E.A., Marr, M.C., Myers, C.B., Morrissey, R.E., and Schwetz, B.A. (1992). Developmental toxicity of boric acid in mice and rats. Fundam. Appl. Toxicol. 18: 266-272.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Mertens, J., Van Laer, L. and Salaets, P. (2011). Phytotoxic doses of boron in contrasting soils depend on soil water content. Plant Soil. 342:73-82.

National Toxicology Program [NTP]. (1987). Toxicology and Carcinogenesis Studies of Boric Acid (CAS No. 10043-35-3) in $B6C3F_1$ Mice. NTP TR 324, NIH Publication No. 88-2580. National Toxicology Program, U.S. Department of Health and Human Services, National Institute of Health.

NICNAS. (2019). Boric acid and precursors to boric acid: Environment tier II assessment. Available on-line: https://www.industrialchemicals.gov.au/sites/default/files/Boric%20acid%20and%20precursors%20to%20boric%20acid_%20Environment%20tier%20II%20assessment.pdf

Price, C.J., Strong, P.L., Marr, M.C., Myers, C.B., and Murray, F.J. (1996a). Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. Fundam. Appl. Toxicol. 32: 179-193.

Price, C.J., Marr, M.C., Myers, C.B., Seely, J.C., Heindel, J.J., and Schwetz, B.A. (1996b). The developmental toxicity of boric acid in rabbits. Fundam. Appl. Toxicol. 34: 176-187.

Thompson, J.A., David, J.C. and Drew, R.E.(1976). Toxicity, uptake and survey studies of boron in the marine environment. Water Research. 10(10): 869-875.

USEPA. (2004). U.S. EPA (United States Environmental Protection Agency). Integrated Risk Information System (IRIS) – Boron and Compounds; CASRN 7440-42-8. Available at: http://www.epa.gov/iris.

Warner et al. (2018). Revised Method for Deriving Australian and New Zealand Water Quality Guideline Values for Toxicants – update of 2015 version. Prepared for the revision of the Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, 48 pp.

Weir, R.J., Jr., and Fisher, R.S. (1972). Toxicologic studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

WHO. (1998). Environmental Health Criteria 204, Boron, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland

2-PROPENAMID (IMPURITY)

This dossier on 2-Propenamid (impurity) (2PA) (CAS RN 79-06-1) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): prop-2-enamide

CAS RN**:** 79-06-1

Molecular formula: C_3H_5NO

Molecular weight: 71.08 g/mol

Synonyms: 2-Propenamide; Acrylamide; Acrylamide solution 50%; EUROAMD

SMILES: C=CC(=O)N

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of 2PA

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Crystalline White solid	1	ECHA
Melting Point	84.5°C at 101.3 kPa	1	ECHA
Boiling Point	Not applicable as substance is solid	1	ECHA
Density	1130 kg/m^3 at 30°C	2	ECHA
Vapour Pressure	Not applicable as substance is solid	1	ECHA
Partition Coefficient (log K_{ow})	-0.9 at 20°C	1	ECHA
Water Solubility	2,155 g/L at 30°C	1	ECHA
Flash Point	Not applicable as substance is solid	1	ECHA
Auto flammability	Not applicable as substance is solid	1	ECHA
Viscosity	Not applicable as substance is solid	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

2-Propenamid is expected to biodegrade and is not expected to sorb substantially to soils or sediments based on the low log K_{ow} and K_{oc} values. In addition, 2-propenamid is not expected to bioaccumulate.

B. Biodegradation

2PA was found to degrade approximately 100% in 28 days in the OECD Closed Bottle Test (301D) (ECHA) [KI Score = 1].

C. Environmental Distribution

No data available (ECHA). However, K_{oc} values of 3.554 L/kg (K_{ow} method) and 5.694 L/kg (MCI method) were estimated using USEPA EPI Suite™ KOCWIN v2.00 module. The estimated log K_{oc} values equal 0.551 and 0.755 for the K_{ow} and MCI methods, respectively [KI Score = 2]. Based on these estimated values, the substance is not expected to sorb substantially to soils or sediments.

D. Bioaccumulation

No experimental data were available for bioaccumulation or bioconcentration of 2PA. However, the log bioaccumulation factor (BAF) determined from regression-based calculations were performed using EPI Suite BCFBAF v3.01. Based on a log K_{ow} of -0.67, the log BAF according to the Arnot-Gobas method for assessing bioaccumulation at the upper trophic level was determined to be -0.047 [KI Score = 2]. The relatively low log BAF suggests 2PA will not bioaccumulate to any substantial degree.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of 2PA is low by the oral, inhalation and dermal routes. It is not irritating to the eyes or skin and is not a skin sensitiser. Repeated exposures of 2PA to rats in a chronic drinking water study exhibited neurotoxicity and carcinogenicity. *In vitro* and *in vivo* studies provide strong evidence that 2PA does not react directly with DNA. It has no reported reproductive or developmental effects.

B. Acute Toxicity

<u>Oral</u>

An EU Method B.1 (Acute Toxicity Oral) study was performed on Sprague-Dawley rats exposed to 2PA. Under the experimental conditions, the oral LD_{50} in rats of acrylamide in aqueous solution at 50% was 354 mg/kg in female rats with 95% confidence interval limits of 305-458 mg/kg. Toxicity was comparable in males. In accordance with the ethic and scientific recommendations concerning the LD_{50} a more precise determination was not conducted. Based on the results of this study, it can be concluded that the acute oral LD_{50} of acrylamide in rats is 177 mg/kg (ECHA) [KI score =1].

Inhalation

An OECD Guideline 433 draft (Acute Inhalation Toxicity: Fixed Concentration Procedure) was employed to estimate the acute inhalation toxicity of 2PA to an unspecified strain of male rat. The results of this test indicate that the 50.7% solution of acrylamide is practically non-toxic by the inhalation route with a LC_0 (60 mins) of 12 mg/L (ECHA) [KI score =2].

Dermal

An OECD Guideline 402 – Acute Dermal Toxicity was employed to estimate the acute dermal toxicity of 2PA to a non-specified strain of rabbit. Rabbits were occlusively dosed at 200, 795, 1,580 and 3,160 mg/kg of 50.7% aqueous acrylamide solution. Solution was applied to unabraided skin. The acute dermal LD_{50} for acrylamide was determined to be 1,141 mg acrylamide/kg bw (ECHA) [KI Score=1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of 2PA using New Zealand White rabbits. Shaved areas of three male animals were treated with 0.5 g per animal of the test article prepared as a paste with 0.086 g of water. A semi-occlusive patch was overwrapped with a gauze binder and secured with tape for an exposure period of 4 hours. Post dosing, excess test article which had not penetrated was wiped away with a gauze pad moistened with water. Animals were observed for 1, 24, 48 and 72 hours after the removal of the bandage. Scoring was conducted according to the scale published in the OECD Guideline (No. 404 – 1992).

Neither erythema nor oedema was observed at any time. It can be concluded from the results obtained under the experimental conditions employed that acrylamide is not irritating to skin (ECHA) [KI score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using 2PA. Three male New Zealand White rabbits received 0.1 mL of undiluted solution in one eye. The other eye remained untreated. The exposure period was 24 hours. Reactions were scored at 1, 24, 48 and 72 hours and at 7, 14 and 21 days post-application to evaluate reversibility of the lesions.

Maximum conjunctivae, chemosis, iris and corneal opacity scores were 2, 2, 1 and 2.3, respectively, which were found to be fully reversible up to 21 days post exposure.

There were no deaths or remarkable body weight changes during the study period. Under the study conditions, 2PA is considered to cause irritation to the eye (ECHA) [KI score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study (i.e., Buehler test) was performed on Pirbright-Hartley guinea pigs. Systemic toxic symptoms after application were not observed at any time during the study. Body weight development was positive and within normal ranges. No erythema nor oedema was observed at any point after the challenge application

in the control group. There were apparently no skin reactions in control animals but 85% of test animals gave a positive response. On the basis of these results, acrylamide should be considered a skin sensitiser in animals (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed using Fischer 344 rats. 2PA was administered orally in drinking water for a period of two years. Dosing levels were given at 0.0, 0.01, 0.1, 0.5 and 2.0 mg/kg/day.

The rats were generally observed twice daily during the work week for overt signs of toxicity or changes in demeanour. These observations included the animals' movement within the cage, the availability of food and water, wastage of feed and the response to the opening and closing of the cage. Routine monitoring on weekends and holidays was limited to the removal of dead animals and animal husbandry procedures required to ensure the availability of food and water.

Parameters monitored during the study included mortality, body weight, food consumption, water consumption, clinical observations, haematology, clinical chemistry, urinalysis, organ weights, gross and histopathology. All rats were examined approximately monthly after the first month for palpable masses. Individual body weights were recorded monthly from all rats.

Overall, ingestion of 2PA induced neurotoxicity in F344 rats at doses ranging from 0.01-2.0 mg/kg/day. Testicular atrophy was observed in rats at elevated doses. The No Observed Adverse Effect Level (NOAEL) was determined to be 0.5 mg/kg in both sexes of rats (ECHA) [KI Score = 1].

Inhalation

No data were available.

Dermal

No data were available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on 2PA based are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on 2PA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Bacterial Reverse Mutation Assay)	-	-	2	ECHA

*+, positive; -, negative.

In Vivo Studies

Acrylamide has been extensively tested in a wide variety of *in vitro* and *in vivo* assays for detection of genetic effects. There is no compelling evidence that acrylamide induces point mutations or interacts with DNA *in vivo* to form DNA adducts. In contrast to point mutation and DNA damage assays, acrylamide induces a variety of chromosomal effects in bone marrow, but studies in spermatogonia are conflicting. Dominant lethal assays have generally produced positive results with acrylamide, which could be explained by chromosomal effects such as deletions. These studies, taken together, provide very strong evidence that acrylamide does not react directly with DNA (ECHA) [Kl Score = 4].

G. Carcinogenicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed using Fischer 344 rats. 2PA was administered orally in drinking water for a period of two years. Dosing levels were given at 0.0, 0.01, 0.1, 0.5 and 2.0 mg/kg/day.

Overall, ingestion of 2PA induced benign thyroid, mammary gland and tunica vaginalis tumours. The NOAEL was determined to be 0.5 mg/kg in both sexes of rats (ECHA) [Kl Score = 1].

Despite National Toxicology Program conclusions that long-term dosing studies using 2PA provide clear evidence of carcinogenicity in rats, the cited study results provided in this dossier are equivocal relative to cancer responses. When evaluating a human relevance table, none of these tumors appear relevant to humans. Humans have substantially different mammary gland physiology from rodents and the tunica vaginalis tumors appear specific for the F344 rat. Only the thyroid may have significance (ECHA).

It should be noted that according to National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2002) acrylamide meets the National Occupational Health and Safety Commission (NOHSC) Approved Criteria (NOHSC, 1999) for classification as a Category 2 carcinogen (Risk Phrase R45 – May cause cancer).

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

Oral

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed on male and female Fischer 344 rats. 2PA was administered orally in drinking water at 0, 0.5, 2.0 or 5.0 mg/kg/day.

Long-term exposure to 2PA in the drinking water, over two generations in Fischer 344 rats, resulted in parental toxicity (reduced bodyweight, clinical signs of toxicity, histologic evidence of axonal swelling and/or degeneration in peripheral nerves) at 5.0 mg/kg/day, accompanied by prenatal lethality. Exposure to 2.0 mg/kg/day resulted in similar but lesser adult toxicity but no prenatal lethality. Exposure to 2.0 mg/kg/day resulted in no change to reproductive parameters in either generation except for reduced body weights and weight gain in F0 males in the pre-breed exposure period and reduced body weight and weight gain in F0 females late in the pre-breed exposure period. The only significant reproductive event induced by 2PA was decreased litter size as a result of dominant lethal mutations.

The NOAEL for all generations was determined to be 2 mg/kg/day (ECHA) [Kl Score = 1].

I. Developmental Toxicity

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed on Sprague-Dawley rats. Animals were dosed daily via oral gavage at 0, 2.5, 7.5 and 15 mg/kg.

Maternal Effects

There were no maternal mortalities and no clear clinical signs of toxicity. When corrected for gravid uterine weight, maternal body weight gain was decreased amongst animals receiving 7.5 and 15 mg/kg/day. The NOAEL for maternal toxicity was determined to be 2.5 mg/kg bw/day.

Developmental Effects

There were no apparent effects on embryo/foetal viability, growth or malformations. There was a slight, but not statistically significant, increase in the incidence of skeletal variations. The most frequently observed variation was the presence of a rudimentary extra lumbar rib. This finding is considered likely to be an indirect consequence of maternal toxicity or stress and is of limited toxicological importance. The NOAEL for developmental effects was determined to be 15 mg/kg bw/day (ECHA) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for 2PA follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Based on health considerations, the concentration of acrylamide in drinking water should not exceed 0.0002 mg/L according to Australian Drinking Water Guidelines Version 3.4. The guideline value for acrylamide of 0.0002 mg/L is based on a consideration of health effects in relation to the limit of determination for analysis using commonly available techniques.

Based on strict health related factors, a health-based derivation was determined as 0.0007 mg/L according to Australian Drinking Water Guidelines Version 3.4. A safety factor of 1,000 is used for the results of an animal study as a basis for human exposure (10 for interspecies variations, 10 for intraspecies variations and 10 for a less than lifetime study). An additional factor of 10 for carcinogenicity was not applied as tumours occur at doses above those that cause neurotoxic effects. The use of this safety factor was recommended by the NHMRC Standing Committee on Toxicity.

B. Cancer

An oral cancer slope factor for 2PA of 5×10^{-1} per mg/kg/day has been developed by USEPA and presented in the Integrated Risk Information System (IRIS) based on thyroid tumours and tunica vaginalis mesotheliomas (USEPA). Health based values will not be derived based on the noted slope factor since NICNAS has determined that the above noted drinking water guidance value is protective of both non-cancer and cancer effects.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2PA does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2PA has low acute and chronic aquatic toxicity.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on 2PA.

Table 3: Acute Aquatic Toxicity Studies on 2PA[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Onchorhyncus mykiss	96-hour LC_{50}	180	1	ECHA
Daphnia magna	48-hour EC_{50}	60	1	ECHA

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pseudokirchneriella subcapitata	72-hour EC_{50}	33 (growth inhibition) 50 (growth rate inhibition)	2	ECHA

Chronic Studies

Fish: A 28-day study was conducted to determine the toxicity of acrylamide monomer to carp (*Cyprinus carpio*). Fish were exposed to 2PA at concentrations of 0, 0.05, 0.5 and 5 mg/L. The NOEC was determined to be 5 mg/L (ECHA) [Kl Score = 2].

Invertebrates: No freshwater invertebrate chronic toxicity data were available (ECHA) [Kl Score = 1].

C. Terrestrial Toxicity

No data were available.

D. Calculation of PNEC

The PNEC calculations for 2PA follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (180mg/L), Daphnia (60 mg/L), and algae (33 mg/L). NOEC values from long-term studies are available for fish (5 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term studies from one trophic level, an assessment factor of 100 has been applied to the lowest reported NOEC value of 5 mg/L. Therefore, the $PNEC_{water}$ is 0.05 mg/L.

PNEC sediment

2PA is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and K_{oc} values, the substance is not expected to bind substantially to sediment. Therefore, a PNEC for sediment has not been calculated.

PNEC soil

2PA is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and K_{oc} values, the substance is not expected to bind substantially to soil. Therefore, a PNEC for soil has not been calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

2PA is an organic substance that has been determined to be readily biodegradable. Thus, it does not meet the screening criteria for persistence.

The relatively low log BAF (-0.047) suggests 2PA will not bioaccumulate to any substantial degree. Therefore, 2PA does not meet the screening criterion for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on 2-PA are > 0.1 mg/L. The acute $E(L)C_{50}$ values from the acute aquatic toxicity studies on 2-PA are > 1 mg/L. Thus, 2-PA does not meet the criteria for toxicity.

Based on PBT assessment guidance cited above, 2PA is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Oral – Acute Tox. 3: H301: Toxic if swallowed.

Dermal – Acute Tox. 4: H312: Harmful in contact with skin.

Inhalation – Acute Tox. 4: H332: Harmful if inhaled.

Skin corrosion / irritation – Skin Irrit. 2: H315: Causes skin irritation.

Serious eye damage / eye irritation – Eye Irrit. 2: H319: Causes serious eye irritation.

Skin sensitisation – Skin Sens. 1: H317: May cause an allergic skin reaction.

Reproductive toxicity: H361: Suspected of damaging fertility or the unborn child.

Germ cell mutagenicity: H340: May cause genetic defects.

Carcinogenicity: H350: May cause cancer.

Specific target organ toxicity: STOT Rep. Exp. 1: H372: Causes damage to organs.

B. Signal word

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if

ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standards for 2-PA in Australia is 0.03 mg/m^3 as am 8-hour time weighted average (TWA). There is also a skin notation indicating that absorption through the skin may be significant source of exposure.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: 2074 (Solid)

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). European Centre for Ecotoxicology and Toxicology of Chemicals The Role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and the Related Food Web. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Technical Report No. 68, Brussels.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS. (2002). Acrylamide Priority existing Chemical Assessment Report No. 23.

NOHSC (National Occupational Health and Safety Commission). (1999). List of Designated Hazardous Substances [NOHSC:10005(1999)]. Sydney, NOHSC.

USEPA. The Integrated Risk Information System (IRIS). www.epa.gov/iris.

2-PROPENOIC ACID, POLYMER WITH SODIUM PHOSPHINATE

This dossier on 2-propenoic acid, polymer with sodium phosphinate does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of 2-propenoic acid, polymer with sodium phosphinate in water treatment. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name: 2-Propenoic acid, polymer with sodium phosphinate

CAS RN: 71050-62-9

Molecular formula: $(C_3H_4O_2.H_3O_2\text{-}P.Na)_x$-

Molecular weight: Variable

Synonyms: 2-propenoic acid, polymer with sodium phosphinate (1:1); 2-propenoic acid, polymer with sodium phosphinate; 2-propenoic acid-sodium phosphinate copolymer; acrylic acid sodium phosphinate polymer; acrylic acid, sodium hypophosphite polymer; acrylic acid-sodium hypophosphite copolymer; phosphinic acid, sodium salt, polymer with 2-propenoic acid; poly(acrylic acid-co-hypophosphite), sodium salt; poly(acrylic acid-co-sodium hypophosphite); sodium hypophosphite-acrylic acid copolymer

2 PHYSICO-CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of 2-Propenoic acid, Polymer with Sodium Phosphinate

Property	Value	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	BioLab Water Additives, 1999
Melting Point	-1 to -3°C	BioLab Water Additives, 1999
Boiling Point	101 to 103°C	BioLab Water Additives, 1999
Specific Gravity	1.20 to 1.24	BioLab Water Additives, 1999
pH	3.5 to 4.5	BioLab Water Additives, 1999
Viscosity	90-150 centistokes (cSt) @ 25°C	BioLab Water Additives, 1999
Water Solubility	Miscible	BioLab Water Additives, 1999

3 ENVIRONMENTAL FATE PROPERTIES

In an OECD 301E test, 2-propenoic acid, polymer with sodium phosphinate degraded 20% in 28 days, indicating that it is not readily biodegradable (BioLab Water Additives, 1999).

As a polymer, 2-propenoic acid, polymer with sodium phosphinate is not expected to bioaccumulate, because its molecular weight will limit its bioavailability.

4 HUMAN HEALTH HAZARD ASSESSMENT

There is very limited information on 2-propenoic acid, polymer with sodium phosphinate.

A technical data sheet on Belsperse® 164 Dispersant (active ingredient: CAS No. 71050-62-9) lists this product as having an acute oral LD_{50} value of >5,000 mg/kg in rats. The product is non-irritating to the skin and eyes (BioLab Water Additives, 1999).

In a letter to the U.S. EPA, male and female rats dosed by oral gavage with a 40% solution of this polymer showed treatment-related signs of osteomalacia associated with hyperphosphaturia and calciuria by week 8 of a 90-day study (U.S. EPA, 2016a).

THE U.S. EPA TSCATS database also has a brief summary of a 4-week rat oral gavage conducted on the product BELSPERSE 164 (CAS No. 71050-62-9). At 5,000 mg/kg-day, there were adverse clinical signs, gross organ pathology and changes in blood biochemical parameters. The NOAEL was 2,000 mg/kg-day (U.S. EPA, 2016b).

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on 2-propenoic acid, polymer with sodium phosphinate is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this polymer.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2-Propenoic acid, polymer with sodium phosphinate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2-Propenoic acid, polymer with sodium phosphinate exhibits low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on 2-propenoic acid, polymer with sodium phosphinate.

Table 2: Acute Aquatic Toxicity Studies on 2-Propenoic Acid, Polymer with Sodium Phosphinate

Test Species	Endpoint	Results (mg/L)	Reference
Rainbow trout	96-hr LC_{50}	>1,000	BioLab Water Additives, 1999
Zebra fish	96-hr LC_{50}	>1,000	BioLab Water Additives, 1999

Test Species	Endpoint	Results (mg/L)	Reference
Daphnia	24-hr EC_{50}	320	BioLab Water Additives, 1999
Algae	72-hr EC_{50}	130	BioLab Water Additives, 1999

Chronic Studies

No studies were located.

C. Terrestrial Toxicity

No studies were located.

D. Calculation of PNEC

The PNEC calculations for 2-propenoic acid, polymer with sodium phosphinate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (>1,000 mg/L), *Daphnia* (>320 mg/L) and algae (>130 mg/L). No long-term studies on 2-propenoic acid, polymer with sodium phosphinate are available. On the basis of the short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 130 mg/L for algae. The $PNEC_{water}$ is 0.13 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot estimate using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$.

PNEC soil

There are no toxicity data for soil-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot be estimated using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$.

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

2-Propenoic acid, polymer with sodium phosphinate is not readily biodegradable. Thus, it meets the screening criteria for persistence.

2-Propenoic acid, polymer with sodium phosphinate is a high molecular weight polymer that is not expected to be bioavailable to aquatic or terrestrial organisms. Thus, it is not expected to bioaccumulate.

No chronic aquatic toxicity studies have been conducted on 2-propenoic acid, polymer with sodium phosphinate. The acute E(L)C_{50} values are >0.1 mg/L. Thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that 2-propenoic acid, polymer with sodium phosphinate is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

10 SAFETY AND HANDLING

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, phosphorus oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for 2-propenoic acid, polymer with sodium phosphinate.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing closed work clothing is recommended.

F. Transport Information

2-Propenoic acid, polymer with sodium phosphinate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

11 DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY INFORMATION

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BioLab Water Additives (1999). Belsperse® 164 Dispersant. General Product Information, http://lpq.com.mx/pdf/BELSPERSE%20164.PDF

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. EPA [EPA] (2016a). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88900000038; accessed October 2016.

U.S. EPA [EPA] (2016b). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88920001980; accessed October 2016.

AMMONIUM CHLORIDE

This dossier on ammonium chloride presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ammonium chloride

CAS RN: 12125-02-9

Molecular formula: ClH_4N

Molecular weight: 53.49g/mol

Synonyms: Salmiac, Sal ammoniac, Ammonium muriate, Ammoniumchlorid, Ammonium chloride ((NH4)Cl), ammoniumchloride, Amchlor, Ammoneric, Darammon, Chlorammonic

SMILES: [NH4+].[Cl-]

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of ammonium chloride.

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	ECHA
Melting Point	338°C	2	ECHA
Boiling Point	Substance is a solid which melt above 300°C and decomposes before boiling.	2	ECHA
Relative Density	1.527	2	ECHA
Vapour Pressure	0	2	ECHA
Partition Coefficient (log K_{ow})	Not relevant - The substance is inorganic.	2	ECHA
Water Solubility	372 g/L at 20°C	2	ECHA
Flash Point	Not relevant - The substance is inorganic solid.	2	ECHA
Auto flammability	Not relevant - The substance is inorganic solid.	2	ECHA
Viscosity	Not relevant - The substance is inorganic solid.	2	ECHA

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

As an inorganic substance, ammonium chloride is not expected to biodegrade, adsorb to sediments or soil nor is it expected to bioaccumulate to any substantial extent.

B. Biodegradation

The inorganic nature of the material suggests that biodegradation is not applicable for this substance (ECHA).

C. Environmental Distribution

Adsorption/desorption

Ammonium chloride is highly soluble in water and soil moisture and is dissociated to the ammonium and chloride ions. Ammonium is bound in soil by the attraction of the positive charge on the ammonium ion to the negatively charged soil micelles. In soil, ammonium is adsorbed primarily by four mechanisms: chemical (exchangeable), fixation (non-exchangeable), reaction with organic matter and physical attractive forces. Since ammonium is so poorly mobile in soil, it is unlikely to leach to groundwater except under unusual circumstances, such as when the cation exchange capacity of the soil is exceeded.

D. Bioaccumulation

Based on the high water solubility and its ionic nature, ammonium chloride is not expected to adsorb or bioaccumulate to a significant extent. Ammonium (ammonia) is a naturally-occurring compound and a key intermediate in the nitrogen cycle. Since it is continually recycled, bioaccumulation, as it is usually considered, does not occur.

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Ammonium chloride is of low toxicity concern.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) study was performed. The study was conducted according to a method whose principle is comparable to the OECD Guideline 401. A test group consisting of 10 animals/sex/dose (Sprague Dawley) was treated by single gavage with an aqueous solution of the test substance. Body weights were monitored during the 14 day observation period. The animals were observed for mortality and for clinical signs of toxicity for a period of 14 days. Decedents were subjected to necropsy. At the end of the observation period, the surviving animals were sacrificed (CO_2 asphyxiation) for the purpose of necropsy. The LD_{50} was determined to be 1, 410 mg/kg bw (ECHA) [KI Score = 1].

Inhalation

It is generally accepted that the principal toxic component of ammonium salts – such as ammonium chloride or -sulphate – is ammonia, rather than the corresponding anion. Therefore toxicity values for ammonium salts (such as: ammonium -sulphates, phosphates, carbonates, chlorides or nitrates), where the major toxic component is ammonia, can be considered as equivalent. Consequently, this hazard assessment comprises the total topic of ammonia toxicity.

Five studies were available for various ammonium compounds, the results based on ammonia are summarized in Table 2 below.

Table 2: Inhalation toxicity test data for ammonia

Test Summary	Species/Sex	Result (LC_{50})	Source
4 hr exposure duration	Rat/Male	> 3.6 mg/m³ air	ECHA [KI Score = 3]
1 hr exposure duration	Guinea pig/ not specified	> 0.81 mg/m³ air	ECHA [KI Score = 3]
8 hr exposure duration	Guinea pig/ not specified	> 800 mg/m³ air	ECHA [KI Score = 3]
4 hr exposure duration	Dog/not specified	> 9.5 mg/m³ air	ECHA [KI Score = 3]
1 hr exposure duration	Rabbit/not specified	> 2.2 mg/m³ air	ECHA [KI Score = 3]

Dermal

An EU Method B.3 (Acute Toxicity (Dermal)) study was available. A preliminary study was performed with Wistar rats (1 male and 1 female) dosed semi-occlusively at 2000 mg/kg body weight for 24 hrs. Slight irritation of treated skin in the female on days 2-4 after application. Duration of observation period following administration was 14 days. The frequency of observations occurred daily while body weights were determined before application and on days 8 and 15. The dermal LD_50 was determined to be > 2 000 mg/kg bw (ECHA) [KI Score = 3].

C. Irritation

Skin

In a dermal study provided in the SIDS Initial Assessment Report For SIAM 17 - Ammonium Chloride (12125-02-9) New Zealand white rabbits were occlusively exposed to 0.5 grams ammonium chloride in 1 mL of water.

For unabraded skin (12 test sites) 7 test sites were scored with a Draize score of 2 while 5 test sites had a Draize score of 3, 24 hours after removal of the test patch. These changes were not observed after 48, 72, 96 hours. No oedema or eschar was found at any observation time point. For abraded (12 test sites; 24 hour observation time point) an erythema score of 2 at 7 sites, and an erythema score of 3 was recorded at 5 sites. These

changes were not observed after 48, 72, 96 hours. No oedema or eschar was found at any observation time point (ECHA) [Kl. score = 2].

Eye

In a primary OECD Guideline 405 eye irritation study, the test substance is applied to the conjunctival sac of one eye in 2 Vienna White rabbits. The substance was tested as powder. The animals were observed after 10 min, 1 hour and 3 hours on the day of treatment and up to 8 days afterwards. The eyes were not washed out after 24 hours as specified in OECD Guideline 405.

The results of testing indicated that ammonium chloride can be classified as a Category 2 eye irritant based on GHS criteria (ECHA) [Kl. score = 2].

D. Sensitisation

A guinea pig maximisation test was performed. Dry powdered ammonium chloride was administered to Pirbright-White (Hoe: DHPK (SPFLac)) guinea pigs. Treated animals displayed no signs of intoxication throughout the entire study duration.

Intradermal injection with Freud's adjuvant (with and without the test substance) led to well defined erythema and slight oedema in control and the treated animals. Very slight to slight oedema appeared at the application sites injected with the test substance in physiological saline (0.9%). Scab formation was noted in all animals. The body weight gain of treated animals was not affected. Only 2 of 10 animals treated with the test substance formulation had a positive reaction. A barely noticeable erythema was seen at the application sites of these animals. The remaining animals showed no irritation effects. The substance was determined to be non-sensitizing (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents) was conducted using male and female Wistar rats. A NOAEL of 1,695.7 mg/kg bw/day was determined based on body weight reduction (ECHA) [Kl. Score = 2].

Inhalation

No adequately or reliable studies are available.

Dermal

No adequately or reliable studies are available.

F. Genotoxicity

In Vitro Studies

An OECD Guideline 471 (Bacterial Reverse Mutation Assay) study was performed. The results of the *in vitro* genotoxicity studies on ammonium chloride are presented in Table 3.

Table 3: *In Vitro* Genotoxicity Studies on ammonium chloride[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay)	-	-	2	ECHA

*+, positive; -, negative

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed. No signs of general toxicity or bone marrow toxicity were observed in this study. Ammonium chloride did not induce micronuclei in the polychromatic erythrocytes (PCE) of the bone marrow of male rats treated up to 500 mg/kg/day (ECHA) [Kl. score = 2].

G. Carcinogenicity

Oral

An OECD Guideline 451 was conducted. In a 30-month feedings study, ammonium chloride (> 99.5% pure) was administered in diet continuously to 50 (5 week-old) Wistar rats/sex/dose at two doses: namely 1.0% and 2.1% for a duration of 30 months (ca. 131 weeks). The control group was presented non supplemented diets. No treatment-related abnormalities in condition or behaviour were observed in the rats of this study.

The clinical effects noted were of random nature and corresponded to the usual ageing symptoms seen in this strain of rats. There were also no adverse compound related effects on mortality, food consumption, haematology, clinical chemistry, urinalysis, or organ weights. The type and incidence of palpable masses noted during the chronic studies did not indicate any treatment-related effects. Body weights were significantly reduced at various periods over the 30-month study period in females of the low dose group and both sexes of the high dose group.

Histopathology examinations revealed dose-related increases in the incidence of zona glomerulosa hypertrophy in all treatment groups in both sexes at the end of the 30-month study. Early increases (after 4 and 13 weeks) in zona glomerulosa hypertrophy were also noted with the high (4%) level of NH4Cl. With 2.1% NH4Cl, the incidence of oncocytic tubules was significantly decreased after 30 months. The overall incidence of nephrosis was comparable among the groups throughout the studies, but after 30 months the incidence of severe nephrosis was decreased in males of the 2.1% NH4Cl group. While a NOAEL for toxicity is 2.1% NH4Cl (1104.6 mg/kg bw), the results of testing were determined to not be

treatment related (ECHA) [Kl. score = 2]. Thus, ammonium chloride is determined to not be carcinogenic.

Inhalation

No studies are available.

H. Reproductive Toxicity

An OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) was performed using Sprague-Dawley rats (ECHA) [Kl. score = 2]. Animals were divided between two subgroups (toxicity and reproductive subgroups). Males of both subgroups and females of the toxicity subgroup were treated until termination during week 6 of treatment. Doses (250, 750 and 1,500 mg/kg/day) were administered to the reproductive subgroup females for two weeks prior to pairing, and throughout pairing and gestation until Day 3 of lactation. Animals that were in parturition at the time of dosing were not dosed that day. Control animals received the vehicle over the same treatment period. Animals were not dosed on their scheduled day of necropsy. A NOAEL of 1500 mg/kg/day for reproduction/developmental toxicity was determined for parental and offspring generations (ECHA) [Kl Score = 1].

I. Developmental Toxicity

Oral

See reproductive toxicity discussion. A NOAEL of 1500 mg/kg/day for reproduction/ developmental toxicity was determined for parental and offspring generations (ECHA) [Kl Score = 1].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

A maximum of 0.5 milligrams ammonia per litre of water has been documented in the Australian Drinking Water Guidelines (ADWG, 2011) for aesthetic considerations. Thus, a drinking water guidance value will not be derived.

A. Cancer

Ammonium chloride was not carcinogenic to rats in chronic oral studies. Therefore, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

CMW does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ammonium chloride is of low acute and chronic toxicity concern to aquatic and terrestrial receptors. Details of relevant studies are provided below.

B. Aquatic Toxicity

Acute Studies

Species mean acute values (SMAV), were considered as relevant endpoints for the assessment of ammonium chloride toxicity. Table 4 lists the results of acute aquatic toxicity studies on ammonium chloride.

Table 4: Acute Aquatic Toxicity Studies on ammonium chloride.

Test Species	Endpoint	Results (mg/L)[1]	Klimisch score	Reference
Oncorhynchus mykiss	96 hr. LC_{50}	42.91	2	ECHA
Prosopium williamsoni	96 hr. LC_{50}	46.27	2	ECHA
Ceriodaphnia acanthina	SMAV[2]	98.5	2	ECHA
Daphnia magna	SMAV[2]	136.6	2	ECHA

1 – tests conducted at pH 8
2 – SMAV = species mean acute value

Chronic Studies

Fish:

Species mean chronic values (SMCV), were considered as relevant endpoints. The lowest species mean chronic value was calculated for *Lepomis macrochirus* (EC20 = 1.35 mg N/L and EC10 = 1.12 mg N/L = 4.28 mg/L ammonium chloride) (ECHA) [Kl. score = 2].

Invertebrates:

The lowest species mean chronic value (EC_{10}, adjusted to pH 8 and 25°C) was 0.66 mg N/L = 2.52 mg/L ammonium chloride for Hyalella Azteca (ECHA) [Kl. score = 2].

Aquatic Plants:

In an 18d-long, static test, growth of Chlorella vulgaris was inhibited by 50% at approximately 2700 mg/L ammonium sulphate (corresponding to 2186 mg/L ammonium chloride). An EC_{50} (5d) of 1300 mg/L was determined for Chlorella vulgaris (ECHA) [Kl Score = 2].

C. Terrestrial Toxicity

Acute toxicity to *Eisenia fetida* was tested in a study according to EPA/600/3-88/029 using ammonium chloride as the test substance (CAS: 12125 -02 -9). The 14d-LC_{50} value was 163 mg/kg soil (ECHA) [KI Score=2].

D. Calculation of PNEC

In aqueous solution, ammonium chloride is completely dissociated into the ammonium ion (NH4+) and the chloride anion (Cl-). Due to the inorganic nature of the substance standard biodegradation testing systems are not applicable. In unsterilized soil, ammonium chloride is mineralized fairly rapidly, and subsequently nitrified. Nitrification and de-nitrification processes also occur naturally in streams and rivers, as well as in many secondary sewage treatment processes. Based on the high water solubility and the ionic nature, ammonium chloride is not expected to adsorb or bioaccumulate to a significant extent (ECHA) [KI Score = 2].

Thus, only PNECwater will be derived.

PNEC Water

The PNEC water is derived based on invertebrate toxicity. The lowest species mean chronic value (EC_{10}, adjusted to pH 8 and 25°C) was 2.52 mg/L Ammonium chloride for *Hyalella Azteca.* Applying an assessment factor of 10 yields a PNECwater of 0.25 mg/L.

PNEC Sediment

Based on the dissociation characteristics of the substance, PNECsediment has not been determined.

PNEC Soil

Based on the dissociation characteristics of the substance, PNECsoil has not been determined.

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ammonium chloride is an inorganic substance for which biodegradability is not relevant. Thus it does not meet the screening criteria for persistence.

Ammonium chloride is an inorganic substance for which bioaccumulation is not relevant. Thus it does not meet the screening criteria for bioaccumulation.

Ammonium chloride is of low toxicity concern and therefore does not meet the screening criteria for toxicity.

Therefore, ammonium chloride is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Harmful if swallowed, H302.

Causes serious eye irritation. H319.

B. Labelling

Warning

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ammonium chloride.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Ammonium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

BUT-2-ENEDIOIC ACID (FUMARIC ACID)

This dossier on but-2-enedioic acid (fumaric acid) presents the most critical studies pertinent to the risk assessment of this substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2E)-but-2-enedioic acid

CAS RN: 110-17-8

Molecular formula: $C_4H_4O_4$

Molecular weight: 116.07 g/mol

Synonyms: fumaric acid, 2-Butenedioic acid, trans-Butenedioic acid, Allomaleic acid, Boletic acid, (2E)-but-2-enedioic acid, Lichenic acid

SMILES: C(=CC(=O)O)C(=O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of But-2-enedioc Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless crystalline solid	2	ECHA
Melting Point	287°C @ 101.3 kPa	2	ECHA
Boiling Point	Sublimes at 200°C; @ 0.23 kPa, fumaric acid sublimes at 165°C	2	ECHA
Density	1640 kg/m^3 at 20°C	2	ECHA
Vapour Pressure	0.02 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-4.02 @ 20°C (Experimental)	2	ECHA
Water Solubility	7 g/L @ 25°C	2	ECHA
Flash Point	Flash point is only relevant to liquids and low melting point solids	2	ECHA
Auto flammability	399°C	2	ECHA
Viscosity	Not applicable as substance is a solid	2	ECHA
Dissociation constant	K1 = 9.3 x 10^{-4} at 25°C K2 = 2.9 x 10^{-5} at 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Fumaric acid is readily biodegradable, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Partitioning

The pKa of fumaric acid is 3.03 and 4.54, indicating that this substance will exist partially in anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts (PubChem).

Volatilisation of fumaric acid from moist soil surfaces is not expected to be an important fate process because the acid exists as an anion and anions do not volatilise (PubChem).

Hydrolysis is not expected to be an important environmental fate process since this substance lacks functional groups that hydrolyse under environmental conditions (PubChem).

C. Biodegradation

The ready biodegradability of fumaric acid was determined using the OECD 301B guideline in a GLP study.

Using a non-adapted sludge from a domestic source, the percentage of biodegradation observed comprised 60.1% after 11 days (i.e., within the 10-day window) and 67.5% after 28 days. The reference substance (sodium benzoate) incubated under the same conditions showed a percentage biodegradation of 60.1% after 11 days. Incubation of the test substance and the reference substance demonstrated that the test substance did not significantly inhibit the microbial activity of the activated sludge.

Accordingly, fumaric acid is considered readily biodegradable [KI score = 1]. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

No experimental data are available for fumaric acid. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} values from the molecular connectivity index (MCI) is 0.865 L/kg. Thus, fumaric acid has a low potential for adsorption to soil and is expected to have very high mobility. Likewise, based on these values along with fumaric acid's high water solubility, if released to water, it will likely not adsorb to suspended solids or sediments.

E. Bioaccumulation

There are no bioaccumulation studies on fumaric acid. The substance has a low potential for bioaccumulation based on log $K_{ow} \leq 3$.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Fumaric acid is an organic dicarboxylic acid and is naturally found in plants and animals. Fumaric acid is approved for use as a food additive in Australia and use as a therapeutic agent in the treatment of psoriasis and other skin disorders, as wells as a feed additive for all animals without a maximum level. Dietary exposure results from the large volumes of fumaric acid used as a food acidulant in applications such as beverages, baking powders and fruit drinks. The Joint FAO/WHO Committee on Food Additives and Contaminants (JECFA, 1999) concluded that there is no safety concern at current levels of intake when used as a flavouring agent (ECHA).

Fumaric acid has low acute toxicity via oral, inhalation or dermal exposure and was practically nontoxic when tested in guideline-comparable studies of acute oral and acute dermal toxicity.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was conducted using male and female Sprague Dawley rats. The substance was administered orally via gavage. The LD_{50} values for the oral administration of fumaric acid in rats range from 9,300 (female rats) to 10,700 mg/kg bw (male rats) (ECHA) [KI Score = 1].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was conducted using female New Zealand white rabbits. Single dose dermal toxicity of fumaric acid using female New Zealand albino rabbits was reported as 20,000 mg/kg (ECHA) [KI Score = 1].

Inhalation

An OECD Guideline 403 (Acute Inhalation Toxicity) was undertaken. An inhalation LD_{50} for rats is reported to be 1,306 mg/L (ECHA) [KI Score = 1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted using small white Russian male and female rabbits. Dermal application of 0.5 g fumaric acid was mildly irritating to the skin of male and female rabbits. Fumaric acid did not elicit dermal reactions that would exceed the threshold for classification in accordance with EU criteria (ECHA) [KI Score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) was undertaken where test material was applied to the lower conjunctival sac of the right eye by pulling away the lower

eyelid. The left eye was treated in one animal. The contralateral eye served as a concurrent, inherent control.

Application of 0.1 g fumaric acid to the eyes of male and female rabbits was considered irritating to the eye and ocular mucous membrane. Fumaric acid is classified as an eye irritant (ECHA) [KI Score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) guinea pig maximisation test was conducted. Fumaric acid shows no sensitisation effect on the skin of female guinea pigs according to the Magnusson-Kligman maximisation test. Fumaric acid is not considered a skin sensitiser.

E. Repeat Dose Toxicity

A Peer-reviewed study comparable to OECD guideline 452 was conducted using male Osborne-Mendel rats over a two-year period.

In a two-year dietary study using male rats, a very slight increase in mortality rate and some testicular atrophy was observed after administration of 1.5% fumaric acid (approximately 750 mg/kg bw/day). Gross and microscopic examination of major organs revealed no abnormalities. The authors of this study concluded that inanition was partly responsible for testicular atrophy. A previous study conducted in a similar manner with female rats showed no adverse effects on reproductive organs after administration of up to 1.2% fumaric acid in the diet for 2 years. Based on the low incidence of mortality of male rats, 1.2% is very near a NOAEL for chronic exposure to fumaric acid (600 mg/kg bw/day). The 1.2% NOAEL (600 mg/kg bw/day) derived from the available long-term rat toxicity data was confirmed as the appropriate point of departure. No non-neoplastic or neoplastic effects were noted supporting the conclusion that the substance is not a carcinogen (ECHA) [KI Score = 2].

F. Genotoxicity

An OECD Guideline 476 (*In Vitro* Mammalian Cell Gene Mutation Test) was performed using mouse lymphoma L5178Y cells. Under the experimental conditions reported, fumaric acid did not induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation. Thus, fumaric acid is not considered to be a mutagen.

G. Carcinogenicity

Fumaric acid is not considered to be a carcinogen and is not classified as such by the International Agency for Research on Cancer (IARC) or the United States Environment Protection Agency (USEPA). In agreement with the regulatory agency, the two-year repeated dose toxicity testing discussed above showed no carcinogenic effects.

H. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed using male and female Charles River CD rats. Substance was administered orally via gavage in a corn oil vehicle at dosage levels of 20, 55 and 150 mg/kg/day.

In a multigeneration reproduction study (similar to OECD guideline 416) maleic anhydride (purity 99%) was administered to 10 male and 20 female rats/dose by gavage at dose levels of 0, 20, 55 and 150 mg/kg bw/day. The rats were mated to produce two generations, each with two litters. Groups of the same size from the second litter were used for subsequent generations and were given the same dose of maleic anhydride as were their parents. Since 100% mortality was observed among parental F1 female rats at 150 mg/kg bw/day, the high dose group was terminated in the F1 generation, and a parental systemic NOAEL of 55 mg/kg bw/day was the highest dose tested in the F1 generation. The study was reduced from a three-generation to a two-generation study.

Renal cortical necrosis occurred in high-dose P/F0 males and females. Increased kidney weights were observed in low- and mid-dose adult F1 females. Therefore, no NOAEL could be determined, and the LOAEL (systemic) was regarded as 20 mg/kg bw/day. With respect to fertility, neither a dose-related reduction nor a pattern (during the two consecutive matings) within the parental (P0) generation suggested a treatment-related effect. No adverse effects on fertility were observed. Based on these observations the NOAEL (fertility) was derived at 55 mg/kg bw/day (highest dose tested under the conditions of this study) (ECHA) [Kl Score = 1].

I. Developmental Toxicity

A peer reviewed dietary study was conducted on an unspecified strain of rat.

Rats were fed 1,000 or 10,000 ppm malic acid, a metabolite of fumaric acid, for 9 weeks prior to mating. One week after weaning of the last F1A litter, the P1 parents were remated to produce the F1B litter. Ten male and 20 female weanlings from each dose group were selected for the P2 generation and administered the appropriate diets. The animals were mated at 100 days of age to produce the F2A generation. One week after weaning of the F2A litter, the P2 parents were remated to produce the F2B litter.

Maternal Effects: Body weight gain of female animals was comparable to controls prior to mating. Body weight gains of male animals in test groups were slightly decreased compared to controls. Feed consumption, survival, appearance and behaviour were similar for P1 test and control rats. The P2 test and control animals were similar throughout the study and wheezing was observed in all groups during the F2B phase. A NOAEL for maternal systemic toxicity was determined to be > 10, 000 mg/kg/day.

Foetal Effects: The F2B generation showed no meaningful differences between test and control animals in the number and placement of implantation and resorption sites or in the number, weight or length of live neonates; none of the neonates died. The skeletal development of F2B neonates was similar between test and control animals. Slight differences in developmental indices were considered to be within the range of normal variations in foetal development and no trend toward lesser or greater skeletal development was observed (ECHA) [Kl Score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for fumaric acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021)

A. Non-Cancer

Oral

The repeated dose NOAEL for fumaric acid is 600 mg/kg/day and will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 600/100 = 6 mg/kg/day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (6 x 70 x 0.1)/2 = 21 mg/L

B. Cancer

The substance is not considered a carcinogen. Thus, a cancer reference value will not be calculated.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Fumaric acid does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Fumaric acid is of low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 presents the results of acute aquatic toxicity studies on fumaric acid.

Table 2: Acute Aquatic Toxicity Studies on Fumaric Acid

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-hour LC_{50}	> 100	1	ECHA
Daphnia magna	48-hour EC_{50}	> 100	1	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	> 100	1	ECHA

Chronic Studies

No data are available.

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for the substance follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (> 100 mg/L), *Daphnia* (> 100 mg/L) and algae (> 100 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported NOEC of 100 mg/L for algae. The $PNEC_{water}$ is 1 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.637 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.8166/1280) \times 1000 \times 1$
$= 0.637$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.0346/1000 \times 2400]$
$= 0.8166\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= -0.865 \times 0.04$
$= 0.03460$ L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg) presented above as 0.865 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.0115 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.0173/1500) \times 1000 \times 1$
$= 0.0115$ mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
$= 0.865 \times 0.02$
$= 0.0173\ m^3/m^3$

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg) presented above as 0.865 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Fumaric acid is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Bioaccumulation of fumaric acid is not expected to occur based on it log K_{ow} value of -4.02 (Table 1). Thus, fumaric acid does not meet the screening criteria for bioaccumulation.

No chronic aquatic toxicity data exist on fumaric acid; however, the acute E(L)C_{50} values are > 1 mg/L in fish, invertebrates and algae. Therefore, fumaric acid does not meet the screening criteria for toxicity.

Therefore, fumaric acid is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H319: Causes serious eye irritation.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention if symptoms persist.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Get medical attention if symptoms persist.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray, powder or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours, or spray Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Pick up mechanically. If formation of dust cannot be avoided use respiratory filter device. Dispose of the material collected according to regulations.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for but-2-enedioic acid.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

But-2-enedioic acid is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1999. Fumaric acid. Summary of evaluations performed by the Joint FAO/WHO Expert Committee on Food Additives.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

PubChem. https://pubchem.ncbi.nlm.nih.gov/compound/Fumaric-acid#section=Computed-Descriptors. Accessed January 2022.

U.S. Environmental Protection Agency [EPA]. (2017). EPI Suite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

CALCIUM CHLORIDE

This dossier on calcium chloride presents the most critical studies pertinent to the risk assessment of calcium chloride in its use as use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA) and the OECD-SIDS documents on calcium chloride (OECD, 2002). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Calcium dichloride

CAS RN: 10043-52-4

Molecular formula: $CaCl_2$

Molecular weight: 110.98 g/mol

Synonyms: Calcium chloride; calcium dichloride; calcium chloride anhydrous

SMILES: Cl(Ca)Cl

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Calcium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White odourless solid; crystals; powder; or granules	2	ECHA
Melting Point	782°C @ 101.3 kPa	2	ECHA
Boiling Point	> 1,600°C @ 101.3 kPa	2	ECHA
Density	2150 kg/m^3 @ 25°C	2	ECHA
Vapour Pressure	-	-	-
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	745 g/L @ 20°C (very soluble)	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Calcium chloride dissociates completely in aqueous solutions to calcium (Ca^{2+}) and chloride (Cl^-) ions. Calcium chloride and its dissociated ions are ubiquitous in the environment.

Because of its dissociation properties and high water solubility, calcium chloride is not expected to be adsorbed to soil. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulfate and carbonate ions. The chloride ion is mobile in soil and eventually drains into the surface water because it is readily dissolved in water (OECD, 2002).

Calcium (Ca^{2+}) and chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (Ganong, 1995). Neither calcium chloride nor its dissociated ions are expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Calcium chloride exhibits low acute toxicity by the oral and dermal routes. It is irritating to the eyes, but not to the skin. There was no toxicity or carcinogenic effects in rats given calcium chloride in the diet for 12 months. Calcium chloride is not genotoxic. No developmental toxicity was reported in pregnant female rats, mice or rabbits given oral doses of calcium chloride.

B. Acute Toxicity

The oral LD_{50} values in rats are 2,301, 4,179 and 3,798 mg/kg (ECHA) [KI score = 2]. The dermal LD_{50} in rabbits is > 5,000 mg/kg (ECHA) [KI score = 1].

C. Irritation

Application of 0.5 mL to the skin of rabbits for 4 hours under occlusive conditions was non-irritating. Erythema and edema scores at all time points were zero (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was moderately irritating. The mean of the 24, 48 and 72-hour scores were: 0.67 for conjunctival redness; 0.78 for chemosis; 1.0 for corneal opacity; and 0.0 for iridial lesions. There were no signs of irritation by Day 21 (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was highly irritating. The mean of the 24, 48 and 72-hour scores were: 1.9 for conjunctival redness; 2.2 for chemosis; 2.0 for corneal opacity; and 1.0 for iridial lesions. The effects were not fully reversible by Day 21 (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was irritating. The mean of the 24, 48 and 72-hour scores were: 1.54 for conjunctival redness; 1.65 for chemosis; 1.0 for corneal opacity; and 0.33 for iridial lesions. The effects were not fully reversible by Day 21 (ECHA) [KI score = 2].

D. Sensitisation

No reliable studies are available.

E. Repeated Dose Toxicity

<u>Oral</u>

Rats were fed a 20 mg calcium chloride/g body weight diet for 12 months. There were no differences in mortality, weight gain or feed consumption between treated and control groups. No neoplastic lesions were observed in the gastrointestinal tract, urinary tract, liver, heart, brain or spleen. The estimated daily intake of calcium chloride is 1,000 to 2,000 mg/kg/day (OECD, 2002) [KI score = 3].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on calcium chloride are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Calcium Chloride

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium*)	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium*)	-	-	2	ECHA
Chromosomal aberration (Chinese hamster lung cells)	-	NC	2	ECHA

*+, positive; -, negative; NC, not conducted.

In Vivo Studies

No studies are available.

G. Carcinogenicity

Rats were fed 20 mg calcium chloride/g diet for 12 months. There were no differences in mortality, weight gain or feed consumption between treated and control groups. No neoplastic lesions were observed in the gastrointestinal tract, urinary tract, liver, heart, brain or spleen. The estimated daily intake of calcium chloride is 1,000 to 2,000 mg/kg/day (OECD, 2002) [Kl score = 3].

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0, 1.76, 8.18, 38 or 176 mg/kg calcium chloride on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 176 mg/kg/day (ECHA) [Kl score = 1].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 1.89, 8.78, 40.8 or 189 mg/kg calcium chloride on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 189 mg/kg/day (ECHA) [Kl score = 1].

Pregnant female Dutch rabbits were dosed by oral gavage with 0, 1.69, 7.85, 35.6 or 169 mg/kg calcium chloride on GD 6-18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 169 mg/kg/day (ECHA) [KI score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived from calcium chloride.

Calcium chloride dissociates in water to calcium and chloride ions. An Australian drinking water guidance value is not available for calcium (ADWG, 2021). The Australian drinking water guidance value for chloride is 250 mg/L based on aesthetics (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Calcium chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Calcium chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on calcium chloride.

Table 3: Acute Aquatic Toxicity Studies on Calcium Chloride

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	4,630	2	OECD, 2002; ECHA
Lepomis macrochirus	96-hour LC_{50}	9,500-11,300	2	OECD, 2002; ECHA
Gambusia affinis	96-hour LC_{50}	13,400	2	OECD, 2002; ECHA
Lepomis macrochirus	96-hour LC_{50}	10,650	2	OECD 2002; ECHA
Daphnia magna	48-hour EC_{50}	2,400	1	OECD, 2002; ECHA
Daphnia magna	48-hour EC_{50}	2,770	2	OECD, 2002; ECHA
Ceriodaphnia dubia	48-hour EC_{50}	1,830	2	OECD, 2002; ECHA
Daphnia magna	48-hour EC_{50}	1,062	2	OECD, 2002; ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	2,900 (biomass)	1	OECD, 2002; ECHA

Chronic Studies

The 21-day EC_{50} and EC_{16} values for calcium chloride in a chronic *Daphnia* reproduction study were 610 and 320 mg/L, respectively (OECD, 2002).

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for calcium chloride follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (4,630 mg/L), invertebrates (1,062 mg/L) and algae (2,900 mg/L). Although a chronic *Daphnia* study is available, an NOEC or EC_{10} was not determined. On the basis that the data consist of short-term and long-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported acute EC_{50} value of 1,062 mg/L from invertebrates. The $PNEC_{water}$ is 11 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. Calcium chloride is highly soluble and dissociates completely in water. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as calcium chloride. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of calcium chloride to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. Calcium chloride dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as calcium chloride. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, no adsorption of calcium chloride to the soil is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Calcium chloride is an inorganic salt that dissociates completely to calcium and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both calcium and chloride ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Calcium and chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Thus, calcium chloride is not expected to bioaccumulate.

A chronic toxicity has been conducted on calcium chloride, but an NOEC or EC_{10} was not determined. The acute E(L)C_{50} values for calcium chloride are > 1 mg/L in fish, invertebrates and algae. Thus, calcium chloride does not meet the screening criteria for toxicity.

The overall conclusion is that calcium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Irritant Category 2

[Note: anhydrous calcium chloride requires the GHS classification Eye Irritant Category 1]

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on the conditions, decomposition products may include the following: hydrogen chloride gas, calcium oxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessarily provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for calcium chloride.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Calcium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2002). OECD-SIDS: Calcium chloride (CAS No. 10043-52-4), UNEP Publications. Available at: https://hpvchemicals.oecd.org/UI/handler.axd?id=cb4247c6-7f28-4ca5-bf69-1f526956b6f9

CERAMIC MATERIALS & WARES, CHEMICALS

This dossier on Ceramic Materials & Wares, chemicals (CMW) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ceramic Materials & Wares, chemicals

CAS RN: 64402-68-4

Molecular formula: Not applicable (UVCB substance)

Molecular weight: Not applicable (UVCB substance)

Synonyms: Antimony oxide calcium titanate silicate ceramic opacifier, Barium calcium magnesium strontium aluminum silicate flux, Calcined bauxite, Calcined clay, Calcined clays, Calcined fireclay, Calcined kaolin

SMILES: Not applicable (UVCB substance)

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of CMW

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	ECHA
Melting Point	1320 °C	2	ECHA
Boiling Point	Not applicable for solids which melt above 300 °C	2	ECHA
Density	2.73 g/cm³ @ 20°C	2	ECHA
Vapour Pressure	Not applicable for solids which melt above 300 °C	2	ECHA
Partition Coefficient (log K_{ow})	Not applicable as substance is inorganic	2	ECHA
Water Solubility	Measured at the maximum of conductivity at pH: 12.50. Calcium: 377- 390 mg/L Aluminium: 225-262 mg/L	2	ECHA

Property	Value	Klimisch score	Reference
Flash Point	Not applicable as substance is inorganic	2	ECHA
Auto flammability	Not applicable as substance is inorganic	1	ECHA
Viscosity	Not applicable as substance is inorganic	2	ECHA

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

As an inorganic substance, CMW is not expected to biodegrade, adsorb to sediments or soil nor is it expected to bioaccumulate to any substantial extent.

B. Biodegradation

No data is available for CMW. However, the inorganic nature of the material suggests that biodegradation is not applicable for this substance (ECHA).

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for CMW. However, the substance is not expected to adsorb to sediments or soil.

D. Bioaccumulation

No experimental data are available for CMW. However, the substance is not expected to adsorb to sediments or soil.

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

CMW is of low acute and chronic toxicity concern to human receptors. Details from animal studies are provided below.

B. Acute Toxicity

Oral: An acute oral toxicity study (limit test) was performed with aluminium hydroxide (SH-20 Muster) in female CRL (WI)BR rats. This study has been performed in accordance with the OECD 423 (17 December 2001), Commission Regulation (EC) No 440/2008, B.1 tris (L 142, 30 May 2008), OPPTS 870.1100 (EPA 712-C-98-190, August 1998) and the Principles of Good Laboratory Practice (Hungarian GLP Regulations: 9/2001. (III. 30) (ECHA) [Kl. score 2].

Inhalation: A study was conducted according to EPA Guidelines for Test Procedures Subdivision F, Series 81-3 and TSCA 40 CFR 798.1150. Five healthy male and five healthy female Wistar Albino rats were exposed to fumed alumina in an inhalation chamber for 4 hours. The number of animals used and the exposure duration were adequate according to the guidelines. Based on the results of this study, the LC_{50} is greater than 2.3 mg/L (ECHA) [Kl. score = 2].

Dermal: An OECD Guideline 402 (Acute Dermal Toxicity) using New Zealand White rabbits. The test item "Weisskalkteig" is most appropriately translated as "white lime paste". As such it is an aqeous paste-like preparation and does not require further moistening in order to ensure good skin contact. 2500 mg/kg was applied to skin of the rabbits over a 24-hr period.

There were no indications of toxic effects from the test sample after dermal application. The dermal LD50 was determined to be > 2500 mg/kg (ECHA) [Kl. Score = 2].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) study was performed using an unspecified strain of rabbit. Semi-occlusive dressings held the test item in place for 3 minutes, 1 hour and 4 hours on the skin of the first animal and for 4 hours for the two other animals.

In the primary dermal irritation study, the skin irritation/corrosion potential of LDSF® RG (Batch No.90121) was tested. 0.5 g of the test substance was applied on the skin of 3 rabbits under semi-occlusive conditions for 3 minutes, 1 hour and 4 hours on the skin of the first animal and for 4 hours for the two other animals.

The application of the test item did not induce colouring of the application site and did not interfere with grading of any skin lesion. Any cutaneous lesion was evaluated at approximately 1 hour, 24 hours, 48 hours, and 72 hours. No other cutaneous lesion was observed. Under the experimental conditions adopted, the test item was found to be a non skin irritant (ECHA) [Kl. score = 2].

Eye

In a primary irritation study, the eye irritation potential of LDSF® LT (Batch No.90122) was tested. 0.1 g of the test substance was introduced into the conjunctival sac of the left eye of each of the four animals. The untreated right eye served as a control. Only one animal was used for the study because LSDF® LT caused local pain and was probably severely irritating or corrosive. Therefore, exposure of two additional animals was not done.

The application of the test item did not induce colouring of the application site and did not interfere with grading of any eye lesion. Any conjunctival, iris and corneal lesion was evaluated at approximately 1 hour, 24 hours, 48 hours and 72 hours for two animals and 8 days, 15 days and 16 days after instillation of LDSF® LT (monitoring was stopped before the end of reversibility period).

Mean indices were calculated from results obtained for each rabbit at 24, 48 and 72 hours. Because ocular lesions and animal pain increased during the reversibility period and under the experimental conditions adopted, LSDF®LT (Batch No. 90122) CMW was determined to be an eye irritant (ECHA) [Kl. score = 2].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study was performed in Guinea pigs (Dunkin Hartley (LAL/HA/BR) using the Magnusson and Kligman method. Methylcellulose (1%), selected based on results from a Preliminary Compatibility Test, was used as the vehicle in this study. Based on the preliminary dose range finding study, 1% (w/v) was used for a first induction stage by intradermal administration. This consisted of three injections to both left and right flanks: an injection with 0.10 mL of Freund's Complete Adjuvant mixed with physiological saline (1:1 v/v); an injection with 0.10 mL of the test item in 1% methylcellulose at the selected concentration; and an injection with 0.10 mL of test item at the appropriate concentration in a 1:1 (v/v) mixture of Freund's Adjuvant and physiological saline. The animals in the control group received three similar injections to each side with the omission of the test item. Again, based on the results of a dose range finding study, 100% (w/v) was used for a second induction stage by dermal application. 0.5 mL of the suspension was applied with occlusion for 48 hours. Two weeks after the last induction exposure, two concentrations were used for the occlusive epicutaneous challenge exposure: 0.5 mL of 75% (w/v) suspension was applied to the left flank of the animals and 0.5 mL of 37.5% (w/v) suspension was applied to the right flank. The test item was applied to the flanks of the test and control animals using a 5x5 cm sterile gauze patch saturated with the test item. The patches remained in place, occluded, for 24 hours. After patch removal, residual test item was removed with a swab and observations were made at 24 and 48 hours. No irritation effects were observed during the dose-range finding study or the induction exposures. In the test group, no positive responses were observed in the treated animal (n=10) with either the 75% (w/v) or 37.5% (w/v) formulations. No positive responses were observed on challenge exposure in the control animals (n=5). In summary, the Guinea-Pig Maximisation test was used to determine the skin sensitisation potential of the test item, aluminium hydroxide. Challenge with the test item produced no positive responses in the previously sensitised test animals or in the control animals. The incidence rate was 0% and the net score 0.00.

Thus, under the conditions of this test, aluminium hydroxide had no detectable sensitisation potential and does not meet EU criteria for classification for sensitisation (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

<u>Oral</u>

An OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test) GLP study was performed. No mortality or clinical signs of intoxication were observed in male and female Wistar rats due to treatment with Al chloride basic at dose levels of 40, 200 and 1000 mg/kg bw/day.

Treatment with Al chloride basic by oral gavage revealed paternal toxicity (irritation effect on glandular stomach mucosa, local effect) at 1000 mg/kg bw/day in both the male and

female Wistar rats. Based on findings observed macroscopically (red foci or thickening of the glandular mucosa of the stomach) and supported by microscopic examination, the maternal/parental NOAEL for local toxic effects on stomach was established at 200 mg/kg bw/day and LOAEL at the level of 1000 mg/kg bw/day, for both males and females.

No reproduction, breeding and early post-natal developmental toxicity was observed in rats at 1000 mg/kg bw/day for males and females. Based on the reported results, a NOAEL for reproduction, breeding and early post-natal developmental toxicity was suggested at a level of 1000 mg/kg bw/day (ECHA) [Kl. Score = 2].

Inhalation

An OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study) was performed on an unspecified rat strain. Intratracheal injection of aluminium powder (Al2O3 dust) caused nodular pulmonary fibrosis in the lungs of the rats only at the highest dose administered (100 mg). An NOAEC was determined to be 70 mg/m³ air (ECHA) [Kl. score = 3].

Dermal

No adequately or reliable studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on CMW based on read-across from aluminium compounds are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on CMW[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (OECD 476) (L5178Y mouse lymphoma cells)	-	-	2	ECHA

*+, positive; -, negative 1 – based on read across to aluminium compounds.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed. No signs of general toxicity or bone marrow toxicity (based on the proportions of immature erythrocytes) were observed in this study. The authors concluded that aluminium hydroxide did not induce micronuclei in the polychromatic erythrocytes of the bone marrow of male rats treated up to 2000 mg/kg/day (ECHA) [Kl. score = 2].

G. Carcinogenicity

Oral

No substance-specific data exist. Based on the weight of evidence approach for carcinogenicity resulting from animal exposure to surrogate substances (aluminium and

calcium dust) and epidemiological studies on cement workers, no classification for carcinogenicity is required (ECHA) (No Kl. score determined).

Inhalation

No studies are available.

H. Reproductive Toxicity

An OECD 426 was performed on Sprague Dawley rats. The ambiguity as to the critical period of exposure and the time-varying water consumption complicate the derivation of a point-of-departure from this study. A LOAEL of 1075 mg AlCitrate/kg bw/day (100 mg Al/kg bw/day) for aluminium toxicity is assigned. The critical effect was a deficit in fore- and hind-limb grip strength in the mid-dose group, supported by evidence of dose response and less consistently observed effects in the mid-dose animals: urinary tract lesions at necropsy (4 males, 1 female); body weight (mid-dose males weighed less than controls in the Day 120 cohort); defecation (more boluses produced by females in the mid-dose group compared with the controls); urination (mid-dose males produced more urine pools than controls); tail pinch (mid-dose females displayed more exaggerated responses); foot-splay (mid-dose females had significantly narrower foot-splay than the controls); and the albumin/globulin ratio (Day 64 mid-dose males had a greater mean ratio than the controls) (ECHA) [Kl. score = 2].

I. Developmental Toxicity

Oral

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed on Wistar rats.

The goal of study is to assess the developmental toxicity and embryotoxic/teratogenic potential of high doses of target compound - Al(OH)3 orally administered to rats during the period of active organogenesis. No significant general/maternal toxicity was observed in any Al treated groups that were orally exposed to Al hydroxide at doses 66.5, 133 and 266 mg Al/kg bw/day.

The results have contributed to the weight of evidence on the lack of pre-natal developmental toxicity of Al hydroxide administered orally to rats at high doses (66.6; 133 and 266 mg Al/kg bw/day (ECHA) [Kl. score = 2].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for CMW follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The OECD Guideline 422 study was selected to determine guideline values. The NOAEL for reproduction, breeding and early post-natal developmental toxicity these studies is 1000 mg/kg-day. The NOAEL of 1000 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 1000/100 = 10 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)
Drinking water guidance value = (10 x 70 x 0.1)/2 = 35 mg/L

B. Cancer

CMW was not carcinogenic to rats in chronic oral studies. Therefore, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

CMW does not exhibit the following physico-chemical properties:

- Explosivity

- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no studies available for “Reaction product of thermal process between 1000°C and 2000°C of mainly aluminium oxide and calcium oxide based raw materials with at least CaO+Al2O3 >80% , in which aluminium oxide and calcium oxide in varying amounts are combined in various proportions into a multiphase crystalline matrix”. As this substance is a UVCB substance with aluminium oxide (AL2O3) and calcium oxide (CaO) as the main constituents, data based on both main components were taken into account by read across following a structural analogue approach. Details from studies on surrogate substances are provided below.

B. Aquatic Toxicity

Acute Studies

Fish:

Thirteen acute toxicity studies for aluminium compounds to fish were found. All the studies are for informational purposes with a total of seven fish species, and are presented for demonstrating the completeness of the literature review. The available 96-h LC_{50}s varied from 0.078 to > 218.6 mg Al/L, and 16-d LC_{50}s ranged from 0.43 to 3.91 mg Al/L. The NOECs (96 h) varied from > 0.07 to > 50 mg Al/L (ECHA) [Kl. Score = 2].

Two short-term studies for calcium dihydroxide with fish were available. The findings for tests on rainbow trout (LC_{50} = 50.6 mg/L) were closely related to the initial pH of the test solutions. Therefore, the initial high pH is considered to be the main reason for the effects of the test item on the fish. The other short-term toxicity study for calcium dihydroxide with the marine species Gasterosteus aculeatus Linnaeus (threespine stickleback) was well described and a dose-response relationship was established (LC_{50} = 457 mg/L) (ECHA) [Kl. Score = 2].

Invertebrates:

Twelve short-term toxicity studies to six aquatic invertebrate species were identified for aluminium compounds. The available 48-h EC/LC_{50} values varied from 0.071 to > 99.6 mg Al/L. The acute NOECs (48 h) varied from > 0.005 to > 0.135 mg Al/L. Most of the variation in results can be explained by differences in hardness and DOC in the test media (ECHA) [Kl. Score = 2].

Two short-term toxicity studies with aquatic invertebrates are available for calcium dihydroxide. One study was conducted with Daphnia magna and the other one with a marine species. The short-term toxicity test with Daphnia magna was carried out according to the OECD 202 guidance taking into account GLP and thus resulting in a Klimish 1 score. The biological findings for Daphnia magna (immobility) were closely related to the initial pH

of the test solutions, which ranged from 7.7 in the controls to 9.5, 9.7, 10.1, 10.7 and 11.1 at 14.8, 22.2, 33.3, 50 and 75 mg Ca(OH)2 /L, respectively. Therefore the initial pH is considered to be the main reason for the effects of calcium dihydroxide on Daphnia magna.

Algae:

Six chronic toxicity studies to a freshwater microalga (Pseudokirchneriella subcapitata) were identified in the literature as Klimisch 1 or 2 studies. ECr10s and ECr50s ranged from 0.051 to 3.15 mg Al/L and 0.024 to 4.93 mg Al/L, respectively. Water quality data for these studies suggest a direct relationship between toxicity and pH, hardness and DOC.

Chronic Studies

Fish:

Four long-term reliable chronic toxicity studies for aluminium compounds to two species of fish (Pimephales promelas and Salveninus fontinalis) were identified as acceptable from the published literature. NOECs and EC_{10}s ranged from 0.088 to 2.3 mg Al/L and 0.078 to 5.19 mg Al/L, respectively (ECHA) [Kl. score = 2].

Invertebrates:

Six long-term chronic toxicity studies to two species of aquatic invertebrates (Ceriodaphnia dubia and Daphnia magna) were identified as acceptable studies. ECr_0 values were calculated using raw data provided from each study using the statistical program Toxicity Relationship Analysis Program (TRAP) version 1.10 from the US EPA National Health and Environmental Effects Research Laboratory (NHEERL). All other endpoints were as reported in each study. NOECs and EC_{10}s ranged from 0.076 to 4.9 mg Al/L and 0.021 to 0.997 mg Al/L, respectively. Water quality data for these studies suggest a direct relationship between toxicity and pH, hardness and DOC. For studies that experimentally manipulated water quality toxicity decreased with increasing pH, hardness and DOC (ECHA) [Kl. score = 2].

C. Terrestrial Toxicity

One short-term and one long-term study with Eisenia andrei are reported using soluble aluminium salts (ECHA). The studies are presented for completeness, but are not considered relevant for assessing the aluminium compounds being assessed in the dossier. In the short-term study, three aluminum salts were tested with an exposure period of 14 days. Three pH (KCl) levels were assessed, namely 3.3, 4.4 and 6.7. Aluminum chloride was most toxic and showed higher toxicity with lower pH levels. At pH (KCl) 4.4, the LC_{50} was 316 mg/kg dw (Al). Al2O3 did not affect survival at concentrations of 5000 mg/kg dw Al at pH levels of 2.4 and 7.1.

D. Calculation of PNEC

The above testing data is based on assumed release of aluminum and calcium from the CMW matrix. However, the substance "Reaction product of thermal process between 1000°C and 2000°C of mainly aluminium oxide and calcium oxide based raw materials with at least CaO+Al2O3 >80% , in which aluminium oxide and calcium oxide in varying amounts

are combined in various proportions into a multiphase crystalline matrix" is a UVCB substance.

In accordance with REACH Annex XI (1907/2006), it is scientifically not possible to determine the dissociation constant for such UVCB substances. Likewise, it is impossible to determine the pKa values of the single constituents in the UVCB by any mathematical calculation.

Based on the above noted information, PNECs are not applicable and will not be determined.

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

CMW is an inorganic substance for which biodegradability is not relevant. Thus it does not meet the screening criteria for persistence.

CMW is an inorganic substance for which bioaccumulation is not relevant. Thus it does not meet the screening criteria for bioaccumulation.

There is data to suggest that aluminium and calcium may potentially exert toxic effects on aquatic receptors. However, there is no data to indicate the extent to which CMW might release aluminium and calcium. Moreover, the extent of aluminium or calcium toxicity appears to be highly related to receiving water chemistry. Therefore, specific toxicity of CMW is uncertain. Thus, CMW does not meet the screening criteria for toxicity.

Therefore, CMW is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Causes serious eye damage H318.

B. Labelling

Danger

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage
Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for CMW.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron, or full body suit will depend on the task.

Eye protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

CMW is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

DIAMMONIUM PEROXODISULPHATE

This dossier on diammonium peroxodisulphate presents the most critical studies pertinent to the risk assessment of diammonium peroxodisulphate in its use in drilling muds. It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Diammonium peroxodisulphate

CAS RN: 7727-54-0

Molecular formula: $H_8N_2O_8S_2$

Molecular weight: 228.21 g/mol

Synonyms: Diammonium peroxydisulfate; Diammonium peroxydisulphate; Diammonium persulfate; Peroxydisulfuric acid (((HO)S(O)2)2O2), ammonium salt (1:2); Peroxydisulfuric acid (((HO)S(O)2)2O2), diammonium salt; Peroxydisulfuric acid, diammonium salt; ammonium persulphate

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diammonium Peroxodisulphate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odourless, crystalline solid	1	ECHA
Melting Point	ND. Decomposes at ca. 393 K (= 120°C) at 100.66 kPa	1	ECHA
Boiling Point	ND. Decomposes at ca. 393 K (= 120°C) at 100.79 kPa	1	ECHA
Density	1260 kg/m³ at 20°C	1	ECHA
Vapour Pressure	0 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	Not applicable as substance is inorganic	-	ECHA
Water Solubility	850 g/L @ 25°C	2	ECHA
Viscosity	ND. Substance is a solid at room temperature	-	ECHA
Dissociation constant (pKa)	Diammonium persulfate dissociates completely to ammonium cation and persulfate anion when it is dissolved in water.	-	ECHA
Flammability	Non-flammable	1	ECHA

ND – not determined

Diammonium peroxidisulphate is widely used in cosmetics and personal care products, perfumes and fragrances, adhesives and sealants, anti-freeze products, coating products, fillers, putties, plasters, modelling clay, non-metal-surface treatment products, inks and toners, leather treatment products, lubricants and greases, polishes and waxes and textile treatment products and dyes.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Diammonium peroxodisulphate dissociates in aqueous media to the ammonium cation and persulfate anion. Biodegradation is not applicable to inorganic compounds. Diammonium peroxodisulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Diammonium peroxodisulphate is not expected to adsorb to soil or sediment because of its dissociation properties and high water solubility.

B. Partitioning

Persulfates dissociate in water to the corresponding cation and persulfate anion. Hydrolysis is temperature and pH dependent. The persulfate anion, independent from the cation, undergoes decomposition in normal water or acid conditions, readily oxidising water to oxygen, producing acid conditions. All degradation products are ubiquitous to the environment (ECHA).

Diammonium peroxodisulphate was shown to be hydrolytically stable at 10°C and pH 4, 7 and 9, a minor hydrolysis was observed at 25°C, whereas a very strong hydrolysis at 60°C was observed within four days. The DT50 at pH 4 and 60°C was determined to be 27.2 h, at pH 7 and 9 and 60°C the DT50 was determined to be 36.5 h. The DT50 at environmentally relevant temperature (12°C) and pH 7 was extrapolated to be 1698.18 h (70.76 d) (ECHA) [Kl. Score = 1].

C. Biodegradation

Biodegradation is not applicable to inorganic compounds.

D. Environmental Distribution

No experimental data are available for diammonium peroxodisulphate. Persulfates are soluble in water and their vapour pressures are negligible. Thus, persulfates released into the environment are distributed into the water compartment in ionic form of the cation and persulfate ion. Persulfates are not expected to sorb to soil due to their dissociation properties, instability (hydrolysis) and high water solubility. They behave as free ions and decompose into sulfate and bisulfate ions. All decomposition products are ubiquitous in the environment (ECHA).

E. Bioaccumulation

There are no bioaccumulation studies on diammonium peroxodisulphate. Substances of the persulfate category are inorganic salts sharing the same anionic persulfate moiety. Persulfates are very soluble in water and are not expected to bioaccumulate in soil or aqueous solutions. They will decompose into organic sulfate or bisulfate (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Diammonium peroxodisulphate is irritating to the eyes, skin and respiratory tract. Inhalation of dust may cause asthma-like reactions. Repeated or prolonged contact may cause skin sensitisation. In a 90-day oral toxicity study in rats, systemic effects (intestinal changes) were observed at the highest dose (200 mg/kg bw/day). It is not carcinogenic or genotoxic, nor does the substance show evidence of reproductive or developmental toxicity.

B. Toxicokinetics/Metabolism

Persulphates are inorganic salts that decompose on heating without a definite melting point at temperatures above 100°C. Due to their properties as inorganic salts and considering their low vapour pressures, an exposure via inhalation is not very likely. Absorption by the skin is also not very likely. Generally, salts largely do not penetrate the skin. Persulphate salts rapidly hydrolyse upon contact with water or water vapour. As a result, persulphates will rapidly degrade and will eventually form the corresponding cations (ammonium, potassium, sodium) and persulphate anions. The persulphate anion, independent of the cation, undergoes further decomposition upon contact with water to form sulphate species. Based on these fundamental properties of persulphates, they are not likely to become bioavailable by inhalation, ingestion or contact by skin.

C. Acute Toxicity

Diammonium persulfate was tested for acute toxicity via the oral, dermal and inhalation routes in rats. In an acute oral toxicity study LD_{50} and LD_0 values of 742 mg/kg bw and 300 mg/kg bw, respectively, in the male rat and LD_{50} value of 700 mg/kg bw in the female rat were determined. In an acute dermal toxicity study LD_{50} and LD_0 values of greater than 2000 mg/kg bw and 2,000 mg/kg bw were determined, respectively. In an acute inhalation toxicity study (whole body exposure) LC_{50} and LC_0 values of greater than 2.95 mg/L and 2.95 mg/L, respectively, were determined.

D. Irritation

Diammonium peroxodisulphate is slightly irritating to the eye and skin of rabbits. Studies in humans indicate that aqueous solutions of 5% persulphate or higher can cause skin irritation.

E. Sensitisation

Results of animal skin sensitisation tests were negative when persulphate was applied topically but were positive when persulphate was injected intradermally. Repeated or prolonged contact may cause skin sensitisation.

F. Repeat Dose Toxicity

In a repeated dose 90-day oral toxicity study in rats (OECD Guideline 408), rats were fed three levels of test material, sodium persulphate (0, 300, 1000 and 3,000 ppm). On day 48 of the study, the concentration of the group receiving 1,000 ppm was increased to 5,000 ppm for the remainder of the study. The body weight of the rats in the two highest dose groups decreased during the last six weeks of treatment. There were no significant differences seen among the groups in urine analytical parameters, haematological blood parameters or both organ weight and body weight ratios. All rats survived the study. Intestinal changes were noted in rats which received 3,000 ppm of sodium persulfate for 13 weeks. These changes were seen more frequently among females than males. The

former received 50 percent more test material than the latter on a dose per body weight basis. No significant changes were seen among the controls or the groups which received 300 ppm, or 1,000 ppm in the diet for eight weeks, followed by 5,000 ppm in the diet for the remainder of the study. No other microscopic changes were noted on comparison among these three groups. LOAEL and NOAEL values of 200 and 91 mg/kg bw/day (3,000 and 1,000 ppm), respectively were determined.

G. Genotoxicity

Diammonium persulphate did not show any mutagenic effects in a bacterial reverse mutation assay.

H. Carcinogenicity

Diammonium persulphate of the persulphate category was tested for its skin carcinogenic potential in a 51-week dermal study with mice following a guideline similar to OECD Guideline 451. Based on the data obtained, diammonium persulphate was not considered carcinogenic. Diammonium peroxidisulphate is not listed in the Chemical Carcinogenesis Research Information System (CCRIS) or International Agency for Research on Cancer (IARC) databases or documented by USEPA as carcinogenic.

I. Reproductive/Developmental Toxicity

Diammonium persulphate was tested for oral reproductive/developmental toxicity in a screening test with rats according to OECD Guideline 421. No test substance-related effects were observed in P and F1 generations. A NOAEL value of 250 mg/kg/day for parental toxicity, reproduction parameters and developmental toxicity was determined. Dose levels were chosen based on the acute lethality studies for the ammonium salt and on a 90-day repeat-dose study in rats with the sodium salt (high dose: 225 mg/kg/day). In the developmental/reproduction study, animals were dosed prior to and during mating through gestation until lactation day 4. There was a transient depression in pup body weight at the 250 mg/kg dose level on lactation day 0 which resolved by lactation day 4. This effect was not considered adverse. Based on the available data, the persulphates do not show evidence of reproductive or developmental toxicity. The NOAEL is 250 mg/kg/day.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diammonium peroxidisulphate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021). There are no existing drinking water guideline values for ammonium ions.

A. Non-cancer

The substance will readily disassociate to its respective cations and anions. As noted above, there are no drinking water guidelines for ammonium ions as there is insufficient data to set a guideline value based on health considerations. The Australian Drinking Water Guideline value for sulphate may apply to sulphate ions (500 mg/L for health and 250 mg/L for taste aesthetic threshold). An ammonia guideline based on aesthetics is however 0.5 mg/L and will be used as drinking water guideline for this dossier.

B. Cancer

A cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diammonium peroxidisulphate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Diammonium peroxodisulphate is of low toxicity concern to aquatic and terrestrial organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on diammonium peroxodisulphate.

Table 2: Acute Aquatic Toxicity Studies on Diammonium Peroxodisulphate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hour LC_{50}	76.3 mg/L	1	ECHA
Daphnia magna	48-hour EC_{50}	120 mg/L	1	ECHA
Phaeodactylum tricornutum	72-hour EC_{10}	320 mg/L	1	ECHA

Chronic Studies

Long-term toxicity testing to fish was considered scientifically unjustified, due to the results obtained in the short-term toxicity to fish studies, the substance's physical-chemical properties and hydrolysis behaviour (ECHA).

An OECD Guideline 211 (Daphnia magna reproduction test) was performed and yielded a 21-day NOEC of 20.8 mg/L based on reproduction (ECHA) [Kl Score = 1].

C. Terrestrial Toxicity

No terrestrial toxicity studies are available.

Persulfates are not expected to be distributed into the terrestrial compartment and consequently not expected to cause toxicity to terrestrial organisms and plants (ECHA).

D. Calculation of PNEC

$PNEC_{water}$

Experimental results are available for three trophic levels. Acute EC_{50} values are available for fish (76 mg/L), Daphnia (120 mg/L) and algae (84 mg/L). On the basis that the data consists of short-term

results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 76 mg/L for fish. $PNEC_{water}$ is 0.076 mg/L.

$PNEC_{sediment}$

No experimental toxicity data on sediment organisms are available. Diammonium peroxydisulphate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} do not readily apply to inorganics, such as diammonium peroxidisulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on these properties, no adsorption of diammonium peroxydisulphate to sediment is to be expected.

$PNEC_{soil}$

No experimental toxicity data on terrestrial organisms are available. The environmental distribution of diammonium peroxydisulphate is dominated by its water solubility. Sorption of diammonium peroxydisulphate should probably be regarded as a reversible situation, i.e., the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as diammonium peroxidisulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, diammonium peroxydisulphate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diammonium peroxodisulphate is an inorganic salt that dissociates to respective cations and anions. Biodegradation is not applicable to these inorganic ions. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Diammonium peroxodisulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Thus, the substance does not meet the screening criteria for bioaccumulation.

Chronic aquatic toxicity data is > 0.1 mg/L and acute aquatic toxicity data is >1 mg/L. Thus, diammonium peroxodisulphate does not meet the screening criteria for toxicity.

The overall conclusion is that diammonium peroxodisulphate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H272: May intensify fire; oxidiser.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335: May cause respiratory irritation.

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Separate eyelids with fingers. Get medical attention.

Skin Contact

Remove contaminated clothing and shoes. Wash skin thoroughly with soap and water. Get medical attention.

Inhalation

If inhaled, remove from area to fresh air. Lay down quietly in recovery position. If breathing is difficult, give artificial respiration with breathing bag. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: sulphur oxides, nitrogen oxides, toxic pyrolysis products.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove. Avoid dust formation. Store in closed containers and dispose of in accordance with federal, state and local regulations. Clean up spill area and treat as special waste.

D. Storage and Handling

General Handling

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust. Take off contaminated clothing and shoes. Wash thoroughly after handling. Do not eat, drink or smoke during work.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids, or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for ammonium persulphate in Australia is 0.01 mg/m^3 as a peak exposure. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Ensure adequate ventilation. Localised ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment

Respiratory Protection: Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Wear suitable protective goggles (tightly fitting). Also wear face protection if there is a splash hazard. Ensure that eyewash stations and safety showers are close to the workstation location.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible. Remove and wash contaminated clothing before re-use. Contaminated work clothing should not be allowed out of the workplace.

F. Transport Information

UN1444 AMMONIUM PERISULPHATE

Class: 5.1

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol, Pharmacol. 25:1-5.

DICOCO DIMETHYL QUATERNARY AMMONIUM CHLORIDE

This dossier on dicoco dimethyl quaternary ammonium chloride (DQAC) (CAS RN 61789-77-3) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. For the purposes of this dossier, a surrogate substance of like composition (Quaternary ammonium compounds, coco alkyltrimethyl, chlorides) (CAS RN 61789-18-2) will be evaluated. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Quaternary ammonium compounds, cocoalkyl trimethyl, chloride

CAS RN: 61789-18-2

Molecular formula: Not applicable (UVCB substance)

Molecular weight: Not applicable (UVCB substance)

Synonyms: Coco alkyltrimethyl ammonium chlorides, Quaternary ammonium compounds, coco alkyltrimethyl, chlorides

SMILES: Not applicable (UVCB substance)

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of DQAC[1]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Amorphous wax-like oyster white solid	1	ECHA
Melting Point	No melting point could be determined, as the test substance undergoes decomposition before melting at a temperature >160°C	1	ECHA
Boiling Point	No boiling point could be determined as the test substance undergoes decomposition before boiling at >160°C.	1	ECHA
Density	0.935 g/cm³ at 20°C	1	ECHA
Vapour Pressure	0.002 Pa at 25°C	1	ECHA
Partition Coefficient (log K_{ow})	2.39 at 20°C	1	ECHA

Property	Value	Klimisch score	Reference
Water Solubility	1,000 mg/L at 20°C	1	ECHA
Flash Point	Flash point is only relevant to liquids and low melting point solids	1	ECHA
Auto flammability	No self-ignition temperature was observed up to the maximum temperature of 405°C	1	ECHA
Viscosity	30.2mm²/s at 20°C	1	ECHA

1 – Data taken from testing on the surrogate quaternary ammonium compounds, coco alkyltrimethyl, chlorides (CAS RN 61789-18-2)

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

DQAC is readily biodegradable, is unlikely to bioaccumulate, and has the potential to bind to soils and sediments. Details of supporting studies are provided below.

B. Biodegradation

An OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test) was performed on DQAC. The test substance at 3 mg/L was incubated with sludge from activated sludge plant treating predominantly domestic waste and O2 consumption was determined over a period of 28 days. The biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand. The test substance reached a biodegradation of 75% at Day 28. Therefore, DQAC is considered readily degradable (ECHA) [KI Score = 2].

C. Environmental Distribution

Adsorption/desorption

An OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) was performed on three soils and read across Quaternary ammonium salts (QAS) category. The experimentally determined mead Koc value of 1,640,329 L/kg is read across from QAS category substance. DQAC is expected to show a similar behaviour in soil (ECHA) [KI Score = 2].

D. Bioaccumulation

No data were available for bioaccumulation of DQAC. However, based on the low log Kow of 2.39, substantial bioaccumulation is not expected (ECHA) [KI Score = 2].

4 HUMAN HEALTH HAZARD ASSESSMENT

A Summary

DQAC is of low acute and chronic toxicity concern to human receptors. Details from animal studies are provided below.

B Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was performed. The study was conducted to determine the acute oral toxicity of the test substance in Sprague-Dawley rats according to OECD 401 and EPA OPP 81-2 Guidelines, in compliance with GLP. Groups of 10 fasted animals (five males and five females per dose except for five males only at the highest dose) were administered 0, 512, 620, 750 or 908 mg/kg bw of the test substance via the oral route. The animals were observed for 14 days after dosing and then sacrificed and subjected to gross pathological examination. There was no mortality in the 512 mg/kg bw group while 3 out of 10 and 7 out of 10 rats died in the 620 and 750 mg/kg bw groups, respectively. All five animals in the highest dose group (908 mg/kg bw) died. Under the study conditions, the acute oral LD_{50} of the test substance in Sprague-Dawley rats was determined to be 684 mg/kg bw (i.e., equivalent to 226 mg a.i./kg bw) (ECHA) [Kl. score =1].

Inhalation

No acute inhalation data were found for DQAC.

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed using New Zealand White rabbits. Under the conditions of the test, the acute dermal LD_{50} for male and female albino rabbits were determined to be 1,300 mg/kg bw (i.e., equivalent to 429 mg a.i./kg bw) and 1,900 mg/kg bw (i.e., equivalent to 627 mg a.i./kg bw) respectively, and the combined dermal LD_{50} was determined to be 1,600 mg/kg bw (i.e., equivalent to 528 mg a.i./kg bw) (ECHA) [Kl Score=1].

C Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of a surrogate quaternary ammonium substance, Coco TMAC (active ingredient 33%), using New Zealand White rabbits. Six animals were treated with 0.5 mL undiluted test substance (33%) in a semi-occlusive patch (1" X 1" gauze) that was overwrapped with a gauze binder and secured with dermiform tape. Plastic restraint collars were applied and remained on the animals for the duration of the 4 h exposure period, after which the tape and test substance were removed. The Draize classification scoring criteria were used to evaluate the irritation potential. Application sites were observed for erythema and oedema at 4, 24, 48 and 72 h after exposure and then daily up to 14 d. The test substance induced moderate erythema and moderate to severe oedema on all sites.

Remission of irritation signs occurred as the study progressed; however, moderate irritation was still present in one rabbit after study Day 12 (erythema: 2 'slight'; edema:1 'barely perceptible'). In addition, desquamation was noted on all sites late in the study period and fissuring was present on two sites. The Primary Irritation Index was calculated to be 5.6

(indicative of moderate irritation). Under the study conditions, due to persistence of irritation reactions in one animal as well as desquamation on all sites and fissuring on 2 sites, the test substance is considered to be severely irritating to skin (ECHA) [Kl. score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using a surrogate substance, quaternary ammonium salt. Nine New Zealand White rabbits received 0.1 mL of undiluted solution in one eye. The other eye remained untreated. The eyelids were held closed for approximately 1 second after instillation. The eyes of three rabbits were washed for approximately 1 minute with 120 mL of lukewarm tap water commencing approximately 30 seconds after dosing. Both eyes were examined for ocular irritation in accordance with the method of Draize approximately 1, 24, 48 and 72 h after dosing and at 96 h and 7, 14 and 21 d. In addition, both eyes of all rabbits were further examined at 72 h and 7, 14 and 21 d with sodium fluorescein and ultraviolet light. Body weights were obtained and recorded on study day 0 (initiation) and at termination (Day 21). Based on the data obtained, the Maximum Average Scores (according to Kay and Calandra scoring system) for the test substance were calculated to be 96.8 (extremely irritating) at 14 d for the unwashed group and 69.7 (severely irritating) at both 72 and 96 h for the washed group. Purulent discharge, clear discharge, petite haemorrhage, blanching, corneal epithelial damage and peeling, corneal neovascularisation, sodium fluorescein stain retention, and vascularised granulation scar tissue was observed in all 6 animals. Same effects were observed in the washed group, except for vascularised granulation scar tissue. There were no deaths or remarkable body weight changes during the study period. Under the study conditions, the test substance is considered to cause irreversible effects on the eye (ECHA) [Kl. score = 1].

Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study (i.e., Buehler test) was performed on Dunkin-Hartley guinea pigs.

The study was conducted to determine the sensitising potential of a read across substance, C12 -14 trimethyl ammonium chloride (TMAC). A pre-test was conducted to determine non-irritating concentrations to be used in the main study. For the main study the induction was carried out at: topical 0.1% w/v in aqueous ethanol for 6 h, repeated after 7 and 14 d. Challenge was done two weeks after the last induction treatment (Day 28): control and test animals received 0.1% w/v in acetone for 6 h on previously untreated site under closed patches. After 18 h the sites were treated with depilatory cream, rinsed and dried. After 3 h, challenge sites were evaluated for erythema on a scale of 0-3. Evaluation was repeated 24 h later. Results of the first grading were: 0/20 (3/20 showed a grade of 0.5; in control 2/10 showed a grade 0.5). Second grading: 0/20 (no erythema was observed in any of the animals); test substance was considered to be non-sensitising (ECHA) [Kl. score = 1].

D Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents) was performed using Sprague Dawley rats. The 90-day study was conducted to determine the oral repeated dose toxicity of the test substance, Coco TMAC. Sprague-Dawley rats were administered the test substance at concentrations of 0, 100, 500 or 2000 ppm (i.e., corresponding to 0, 22, 113 and 273 mg/kg bw/day in males and 0, 25, 121, 297 mg/kg bw/day in females) in the diet for 90 d. The active ingredient dose equivalent was calculated to be 0, 7.9, 40.3 and 96.9 mg a.i./kg bw/day in males and 8.8, 42.9, 105.3 mg a.i./kg bw/day in females. The highest dose of 2000 ppm was reduced to 1000 ppm from Day 29 onwards due to deterioration in health of the test animals at 2000 ppm. At the highest dose, the treatment-related findings were clinical signs of toxicity, reduced body weight gain and food efficiency, organ weight changes and microscopic changes in the spleen and kidneys. At the mid dose, reduced body weight gain (males) and reduced food consumption, reduced absolute heart weight and higher incidence of haemosiderin accumulation in the kidneys of males was observed. No treatment-related effects were observed at the lowest dose. Based on the results of the study, dietary administration of the test substance to rats for a period of 90 d at levels up to 273 mg/kg bw/day resulted in toxicologically significant effects at the high dose and marginal effects at the next lower dose of 113 mg/kg bw/day (500 ppm). No such effects were demonstrated at the lowest dose of 22 mg/kg bw/day (100 ppm). The changes observed at the mid dose (500 ppm) were considered to be minor, isolated effects associated with the reduced palatability of the test substance and were considered not to represent an adverse health effect. Therefore, based on effects on body weight, food efficiency and clinical signs the study authors established the NOAEL at the mid dose level of 500 ppm (i.e., equivalent to 40.3 mg ai./kg bw/day) (ECHA) [Kl. Score = 1].

Inhalation

No data were available.

Dermal

An OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study) was performed on New Zealand White rabbits. The 28-day study was conducted to determine the repeated dose dermal toxicity of the read across substance, C16 TMAC, in New Zealand albino rabbits (both sexes).

The purity was not specified and the study included a lower than recommended number of animals (i.e., 10/group rather than 20/group as per guideline) and histopathology was performed only on limited organs. The test substance (0 and 10 mg test substance/kg bw/day) was applied to the shaved, intact skin of groups of 5 New Zealand albino rabbits/sex/group for 6.5 to 7 hours, 5 days/week for 4 weeks.

Dermal irritation readings were recorded daily. The animals were weighed weekly during the exposure period. Blood was collected for haematology measurements before initiation of dosing and prior to termination. Liver and kidneys weights were recorded at necropsy and

limited histopathology was conducted. There were no systemic treatment-related effects on body weights, haematology, organ weights, gross necropsy findings or histopathology. Treated areas of the skin showed mild to marked acanthosis with active mitosis, hyperkeratosis, and partial to extensive necrosis of the epidermis and hair follicles, partly with encrustation and exudate. Based on the results of the read across study, the NOAEL for systemic effects of DQAC (by read across to Coco TMAC therefore can be considered to be at 10 mg/kg bw/day (ECHA) [Kl Score = 2].

E Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on DQAC based on read-across from aluminium compounds are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on DQAC[1]

Test System[1]	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Bacterial Reverse Mutation Assay)	-	[1]	2	ECHA

*+, positive; -, negative

1 – based on read across to Coco TMAC.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed. The study was conducted to determine the clastogenic potential of a surrogate test substance, Coco TMAC (active ingredient 33%). Based on the results of a dose range finding assay, a dosage of 468 mg/kg bw (in1% methyl cellulose) was administered by oral gavage to male and female mice. Following dosing, the animals were examined regularly for any clinical signs of reaction.

Bone morrow smears were obtained at 3 sampling times: 24, 48 or 72 hours after dosing. One smear from each animal was examined for the presence of micronuclei in 1000 polychromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes was assessed by examination of at least 1000 erythrocytes from each animal. A vehicle control (1% methylcellulose) and a positive control with mitomycin C by intraperitoneal injection were included. At all sampling times, mice treated with the test substance showed no significant increase in the frequency of micronucleated polychromatic erythrocytes. There was no significant decrease in the ratio of polychromatic to normochromatic erythrocytes at any of the three kill times after treatment. The positive control compound, mitomycin C, produced large, highly significant increases in the frequency of micronucleated polychromatic erythrocytes together with large decreases in the ratio of polychromatic to normochromatic erythrocytes and increases in the frequency of micronucleated normochromatic erythrocytes. Under the conditions of the study, the test substance, and by

association DQAC, was found to show no evidence of clastogenic potential in the bone marrow cells of mice (ECHA) [Kl. score = 1].

F Carcinogenicity

Oral

No substance specific data exist.

Inhalation

No studies are available.

Dermal

No studies are available.

G Reproductive Toxicity

Oral

See discussion on developmental toxicity below.

H Developmental Toxicity

Dermal

There are no oral developmental toxicity studies of DQAC. However, there is a dermal developmental toxicity study (OECD Guideline 414 - Prenatal Developmental Toxicity Study) of QAS category using C16 TMAC as a surrogate.

The study was conducted in New Zealand White rabbits. Twenty mated female rabbits per group were exposed topically (daily for 2 hours) from Days 7 to 18 of gestation at concentrations of 0, 0.5, 1.0, or 2.0% (equivalent to 0, 10, 20 and 40 mg a.i./kg bw/day, respectively). The control group was treated with deionised water only. Clinical condition and reactions to treatment were recorded at least once daily. Body weights were recorded on Days 0, 3, 6, 9, 12, 15, 18, 21, 24, 27 and 29 of gestation. All surviving females were sacrificed on Day 29 of gestation and the foetuses were removed by caesarean section. At necropsy the females were examined macroscopically. Live foetuses were weighed, sexed and were examined for visceral and skeletal abnormalities. Two control animals, one intermediate and one high dose died during the study. Two of the rabbits that died were aborted prior to death (one control and one intermediate dose). Two additional abortions occurred, one each in the intermediate and high dose groups. Deaths or abortions were not considered to be related to the test substance.

No treatment-related maternal body weight or food intake effects were noted. The incidence of foetal malformations, as well as genetic and developmental variations in the treated groups was comparable to that of the control group. No other treatment-related

effects were noted. Under the study conditions, the NOAEL of DQAC for maternal as well as developmental toxicity is considered to be 40 mg/kg bw/d in rabbits [Kl. score = 1].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for DQAC follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The repeated dose NOAEL for DQAC has been determined to be 40.3 mg ai./kg bw/day. Thus, the NOAEL of 40.3 mg/kg-day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 40.3/100 = 0.4 mg/kg-day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.4 x 70 x 0.1)/2 = 1.4 mg/L

B. Cancer

No data on carcinogenicity was available. Therefore, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

DQAC does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Details from studies on surrogate substances are provided below.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on DQAC.

Table 3: Acute Aquatic Toxicity Studies on DQAC[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Salmo gairdneri	96 h LC_{50}	3.2	2	ECHA
Daphnia magna	48 h EC_{50}	0.09	2	ECHA
Pseudokirchneriella subcapitata	72 h EC_{50}	0.062	2	ECHA

1 – data abstracted from quaternary ammonium compounds, Coco TMAC

Chronic Studies

Fish:

A study was conducted to determine the long-term toxicity to Fathead minnow (Pimephales promelas) of the read-across substance, C12-16 ADBAC (purity: 30%). Mortality, hatchability and growth were evaluated. Fish eggs (80 per concentration) were exposed for 34 d to mean measured concentrations of 0, 32.3, 75.9, 134.2, 186.8, 273.2 and 488.7 mg a.i./L of the radiolabelled test substance. Analytical determination was performed and the sample concentrations were verified by liquid scintillation counting. After 7 d, surviving fry from two replicates were thinned to 10 animals per replicate for each exposure group (total of 20 animals per concentration) and exposed to the same concentrations for a 28 d post-hatch static renewal toxicity test. Observations of symptoms and mortality were conducted daily. Under the conditions of the study, the 34 d NOEC for hatchability was 0.274 mg/L, the 34 d

NOEC and LC_{50} for survival were 0.032 and 0.094 mg a.i./L, respectively, and the 34 d NOEC for growth was
> 0.032 mg/L. Based on the results of the read across study, the 34 d NOEC of 0.032 mg/L is considered relevant for DQAC (ECHA) [KI Score = 2).

Invertebrates:

A study was conducted to determine the long-term toxicity to aquatic invertebrates of the read across substance, C16-18 and C18-unsaturated TMAC as a suitable surrogate for DQAC according to OECD Guideline 211.

Daphnia magna were exposed to six concentrations of the test substance in a 21-day static-daily renewal test in three different water types (i.e., laboratory blended water, well water and river water).

Analytical determination of the test substance was performed. Measured concentrations (µg/L; values represent the geometric mean of the 0- and 24-hour concentration analyses) were southwest well water at 1.6, 3.1, 6.8, 14.6, 30.6 and 60.8 µg a.i./L and river water at 35.7, 53.4, 68.3, 99.1, 122.3 and 309.3 µg a.i./L. The test in blended water was discontinued after 14 d due to inadequate reproduction by control organisms.

Mortality was monitored daily and the number of young produced in each beaker was recorded. Test substance concentrations were verified by analysis and represent the geometric mean of the 0 and 24 h concentration. Under the test conditions, the 21d NOEC of the test substance to *Daphnia magna* was equivalent to 0.0068 and 0.099 mg/L in southwest well and river water, respectively. The NOEC for DQAC was considered equal to 0.0068 mg/L (ECHA) [KI Score = 2].

C. Terrestrial Toxicity

No data were available.

D. Calculation of PNEC

The PNEC calculations for DQAC follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. The lowest acute EC_{50} value was 0.062 mg/L. On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported EC_{50} value of 0.062 mg/L. Therefore, the PNECwater is 0.00062 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the substance is expected to substantially disassociate to partition to sediments. Nonetheless, a PNECsed

was calculated using the equilibrium partitioning methodology. The PNECsed is 15.5 mg/kg sediment wet weight.

The calculations are as follows:

PNECsed = (Ksed-water/BDsed) x 1000 x PNECwater
= (3.2x10^4/1280) x 1000 x 0.00062
= 15.5

Where:

Ksed-water = suspended matter-water partition coefficient (m^3/m^3)
BDsed = bulk density of sediment (kg/m^3) = 1,280 [default]

Ksed-water = 0.8 + [(0.2 x Kpsed)/1000 x BDsolid]
= 0.8 + [(0.2 x 1.25x10^5/1000 x 1,280]
= 3.2x10^4

Where:
Kpsed = solid-water partition coefficient (L/kg)
BDsolid = bulk density of the solid phase (kg/m^3) = 2,400 [default]

Kpsed = Koc x foc
= 3.1x10^6 x 0.04
= 1.2x10^5

Where:

Koc = organic carbon normalised distribution coefficient (L/kg). The Koc was calculated as the midpoint of modelled Koc range and determined to be 3.1x10^6 L/kg.
foc = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The PNECsoil is 25.6 mg/kg soil dry weight.

The calculations are as follows:

PNECsoil = (Kpsoil/BDsoil) x 1000 x PNECwater
= (6x10^4/1500) x 1000 x 0.00062
= 25.6

Where:

Kpsoil = soil-water partition coefficient (m^3/m^3)
BDsoil = bulk density of soil (kg/m^3) = 1,500 [default]

Kpsoil = Koc x foc
= $3.1x10^6$ x 0.02
= $6.2x10^4$

Where:

Koc = organic carbon normalised distribution coefficient (L/kg). The Koc was calculated as the midpoint of modelled Koc range and determined to be $3.1x10^6$ L/kg.
Foc = fraction of organic carbon in soil = 0.02 [default].

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

DQAC is an organic substance that has been determined to be readily biodegradable. Thus, it does not meet the screening criteria for persistence.

The estimated log Kow is equal to 2.39. Based on the log Kow, DQAC will not have a tendency to bioaccumulate (ECETOC, 2000). Therefore, DQAC does not meet the screening criterion for bioaccumulation.

DQAC is a high toxicity concern based on the results presented in Table 3. Thus, DQAC does meet the screening criteria for toxicity.

However, based on PBT assessment guidance cited above, DQAC is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Acute toxicity - oral

Acute Tox. 3 H301: Toxic if swallowed.

Acute toxicity - dermal

Acute Tox. H311: Toxic in contact with skin.

Skin corrosion / irritation Skin Corr. 1C H314: Causes severe skin burns and eye damage.

Serious eye damage / eye irritation

Eye Damage 1 H318: Causes serious eye damage.

B. Labelling

Danger

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for DQAC.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls

to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be an effective type of air-purifying respirator: organic vapor cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

DQAC is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). Persistent organic pollutants. Response to UNEC/INC/ CEG-1. Annex 1, Document No. 41. Brussels, Belgium.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

DISTILLATES (PETROLEUM), SOLVENT-DEWAXED HEAVY PARAFFINIC

This dossier on distillates (petroleum), solvent-dewaxed heavy paraffinic (DPHP) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Solvent-dewaxed heavy paraffinic distillate

CAS RN: 64742-65-0

Molecular formula: Not applicable (UVCB substance)

Molecular weight: ≥ 72 - ≤ 828 g/mol

Synonyms: None available

SMILES: Not applicable (UVCB substance)

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of Distillates (petroleum), Solvent-dewaxed Heavy Paraffinic

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Liquid	1	ECHA
Melting Point	-60°C to 0°C	2	ECHA
Boiling Point	200°C to 800°C	2	ECHA
Density	0.81 to 0.97 g/cm^3 at 15°C	2	ECHA
Vapour Pressure	<0.1 hPa at 20°C	2	ECHA
Partition Coefficient (log K_{ow})	1.99 to 18.02 Midpoint of these values is log Kow = 8[1]	2	ECHA
Water Solubility	2.69E-12 to 2000 mg/L [1]	2	ECHA
Flash Point	>115 to 268°C	2	ECHA
Auto flammability	NA	2	ECHA
Viscosity	1.99 to 847 mm^2/s at 40°C	2	ECHA

1 - Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance.

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

DPHP is inherently biodegradable. There is a potential for bioaccumulation given the large range of Kow values for single constituents of the distillate mix. However, the inherent biodegradability of the substance suggests that bioaccumulation of the distillate mix would be mitigated. Similarly, binding to soils and sediment may occur but environmental degradation is expected to reduce the extent of sorption. Details of supporting studies are provided below.

B. Biodegradation

In a biodegradability study, Solvent Neutral 600 Base Oil (MRD-94 -981) was determined to be inherently biodegradable but not readily biodegradable with a mean degradation of 31.13% by day 28 (ECHA)[KI Score = 2].

C. Environmental Distribution

Adsorption/desorption

The substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. Calculated log K_{oc} for constituents of this substance range between 1.71 and 14.70. A midpoint for these data is 6.495 resulting in a K_{oc} value of $3x10^6$. Note that this is the full range of predicted values and that this may be misleading or unrepresentative of the properties of the UVCB substance as a whole (ECHA) [KI Score = 3].

D. Bioaccumulation

The substance is a hydrocarbon UVCB. Standard tests for this endpoint are intended for single substances and are not appropriate for this complex substance. Calculated BCF for constituents of this substance range between 0.4 and 71,100 L/kg. Note that this is the full range of predicted values and that this may be misleading or unrepresentative of the properties of the UVCB substance as a whole (ECHA) [KI Score = 3].

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

DPHP is of low acute and chronic toxicity concern to human receptors. Details from animal studies are provided below.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was performed. Paraffinic oil sample API 78-9 (CAS No. 64742-56-9) was administered via oral gavage to five Sprague-Dawley rats per sex at a single dose of 5,000 mg/kg (5 g/kg).

The rats were observed for clinical signs of toxicity, changes in body weight, and other gross abnormalities over a 14-day post-exposure observation period. All rats were killed and necropsied on day 14.

No mortalities or any sign of clinical sign of toxicity were observed in either male or female rats dosed at 5,000 mg/kg. Body weight gain was observed to be normal in all animals. One animal did exhibit hydronephrosis in the right kidney but this was not considered to be treatment-related. Necroscopy did not reveal any gross abnormalities in either male or female rats.

The acute oral LD_{50} was determined to be >5,000 mg/kg (ECHA) [Kl. score =1].

Inhalation

An OECD Guideline 403 (Acute Inhalation Toxicity) study was performed.

A group of five male and five female rats were exposed for 4 hours to an aerosol of the test material at a target concentration of 5 mg/L. Four additional groups of rats were then exposed for 4 hours to target aerosol concentrations of 1, 1.5, 2.5 and 3.5 mg/L. A control group exposed, in the chamber, to air only was also included. Animals were observed continuously during the first hour of exposure, hourly for the remainder of the exposure and once daily for the 14-day post exposure period. Mortalities were recorded and body weights were measured prior to exposure and again 7 and 14 days after exposure. On the 14th day post-exposure, necropsies were performed on all surviving animals. For all animals, including animals found dead, the lungs and any other abnormal tissues were removed and fixed for subsequent histopathological examination.

The LC_{50} for males and females was 2.18 mg/L with 95% confidence limits at 1.80 to 2.55 mg/L for insufficiently refined lubricant base oil (ECHA) [Kl. score = 1].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed using New Zealand White rabbits. API 78-9 was administered to four New Zealand White rabbits/sex at a dose of 5000 mg/kg for 24 hours. Prior to application of the test material, the exposure sites of four rabbits were abraded by making epidermal incisions. The remaining four rabbits were left unbraded. Another group of eight (four/sex) rabbits were used as control animals.

Behavioural reactions were monitored through the 24-hour contact period. Mortality, clinical signs of toxicity and behavioural abnormalities were observed twice daily through the 14-day post-exposure observation period. Body weight was recorded for all animals on Day 0, 7 and 14 of the study period. On Day 14 all animals were necropsied and observed for gross pathological changes.

Dermal administration of residual oils (petroleum), catalytic dewaxed (API 78-9)at 5000 mg/kg did not result in any dermal irritation or signs of clinical toxicity. Gross necroscopy did not reveal any signs of systemic toxicity at the 5000 mg/kg dose level.

The acute dermal LD_{50} for API 78-9 is greater than 5000 mg/kg (ECHA) [Kl Score=1].

C. Irritation

Skin

In a primary dermal irritation study, six New Zealand White rabbits (three male/three female) were dermally administered 0.5 mL solvent dewaxed light paraffinic oil (API 78-9, CAS RN64742-56-9) under occlusive wrap for 24 hours. After the exposure period, the bandages were removed and test sites were wiped with gauze sponges. The animals were observed thereafter and dermal irritation was scored using the Draize method at 24 hours, 72 hours and on Day 7 post-exposure.

Oedema was not apparent in male or female rabbits at any observation point. Very slight erythema was evident in all male and female rabbits at the 24-hour observation point. Very slight erythema was observed in only one male rabbit by the 72-hour observation point and no irritation was visible in any test animal by the end of the 7-day observation period. No differences in irritation were observed between intact and abraded skin sites.

Solvent dewaxed light paraffinic oil is not considered to be irritating to the skin of rabbits (ECHA) [Kl. score = 2].

Eye

In a primary eye irritation study, six New Zealand White rabbits (three male, three female) had 0.1 mL of dewaxed light paraffinic oil instilled into the conjunctival sac of their right eye. The left eyes of these rabbits served as treatment controls. Additionally, three rabbits (two male, one female) were administered the test material in the right eye and the eyes were rinsed with warm water 30 seconds following exposure.

Ocular lesions were observed for at 24, 48 and 72 hours post-exposure and fluorescein dye evaluations employed for each reading. Grading and scoring of ocular irritation was performed according to the Draize method.

Rabbits with washed eyes exhibited no irritation through the 72-hour observation period. A single male rabbit in the unwashed group exhibited conjunctival chemosis at the 48-hour observation period. The remaining rabbits showed no signs of irritation through the study period.

Solvent dewaxed light paraffinic oil is not considered to be an ocular irritant (ECHA) [Kl. score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) was performed . This study was performed in Hartley Guinea pigs.

In the induction phase of a skin sensitisation study, 0.4 mL of a 50% mixture of test material and paraffin oil was applied under an occlusive dressing to the shorn skin of 10 male and 10 female animals. Six hours after application, the dressings were removed and the skin wiped to remove residues of test material. The animals received one application each week for three weeks. The same application site was used each time. Two weeks following the third

application, a challenge dose (0.4 mL of a 1% mixture in paraffin oil) was applied in the same manner as the sensitising doses. A previously untreated site was used for the challenge application. The application sites for induction and challenge doses were read for erythema and oedema 24 and 48 hours after patch removal. To assist in the reading of the response to the final challenge dose, the test site was depilated three hours prior to reading by using a commercially available depilatory cream. 2,4-dinitrochlorobenzene at 0.3% in 80% aqueous ethanol was used as the positive control in the induction phase and 2,4-dinitrochlorobenzene in acetone was used as the positive control in the challenge phase. Vehicle control and naive control groups were included in this study and the procedure for these was the same as for the test groups.

In the challenge phase, one animal in the treatment group exhibited a very slight erythema reaction. No animals exhibited reaction in the naive or vehicle control group. In the positive control group, 20 animals exhibited a very slight to severe irritation reaction. The reactions of 18 animals exceeded the highest reaction observed in the naive positive control animals. In the naive positive control group, three animals exhibited very slight erythema reactions. Based on these results, the test material is not considered to be a skin sensitiser under the conditions of this study (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents) was performed. Heavy paraffinic distillate aromatic extract was administered to 10 male Sprague-Dawley rats/dose at dose levels 0, 125 or 500 mg/kg bw/day 5 days a week for 13 weeks. Four of 10 mice in the 500 mg/kg/day group were sacrificed prior to scheduled termination. All animals in the 125 mg/kg/day survived to date of sacrifice. No details on clinical signs were provided. Body weight was significantly reduced in the 500-mg/kg/day group. A significant decrease ($p<0.05$) was shown in red blood cell (RBC) parameters (including RBC count, haemoglobin and haematocrit) and platelet in males dosed orally at 500 mg/kg/day. Males orally dosed at 125 mg/kg/day showed a significant decrease in RBC parameters; platelet counts were slightly decreased in these rats but did not achieve statistical significance. There were no significant differences in the RBC morphology or white blood cell (WBC) differential data. The only statistically significant difference between the serum data from control and orally dosed rats was observed for SDH (0 mg/kg/day = 5±2 IU/l, 150 mg/kg/day = 8±2 IU/l, 500 mg/kg/day = 9±7 IU/l). Treatment-related dose-dependent changes in relative organ weights included increased liver weight in both groups, decreased prostate weight in both groups, decreased seminal vesicle weight in the high-dose group, and decreased thymus weight in both groups. Focal areas of red discoloration and/or generalized reddening were also observed in the brain, spinal cord, stomach and testes of many of the rats dosed orally at 500 mg/kg/day. Treatment-related histopathology was generally dose-dependent and occurred in the following tissues: adrenals, bone marrow, liver, stomach and thymus. Atrophy occurred in the male sex organs (testes, seminal vesicle and prostate). Sperm evaluations showed a significant increase in the frequency of sperm with abnormal heads in the rats dosed orally at 500 mg/kg/day (1.9% in controls and 3.2% in treated rats).

A NOAEL for heavy paraffinic distillate aromatic extract could not be identified and is less than 125 mg/kg/day when administered orally (ECHA) [Kl. Score = 1].

Inhalation

An OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study) was performed on Sprague-Dawley rats. One of two lubricant base oils [solvent-refined oil (SRO) and severely hydrotreated, hydrocracked oil (HBO)] was administered to Sprague-Dawley rats (10/sex/dose) by dynamic inhalation exposure at nominal concentrations of 0, 50, 220 or 1000 mg/m^3 for 6 hours per day, 5 days per week for approximately 4 weeks (, 17 days for SRO, and 20 days for HBO). The mass median aerodynamic diameter was approximately 1µm.

Foamy macrophages accumulated in the lungs of exposed animals with each material in a concentration-related manner, especially in alveoli close to alveolar ducts. Mild infiltration of polymorphonuclear leukocytes (PMNs) into alveoli was noted also with high aerosol concentrations. Increased numbers of alveolar macrophages are expected following deposition of a significant number of particles in the alveoli. The alveolar macrophages and the associated increase in neutrophilic leukocytes are part of the normal mechanism for removal of an increased particle load. The presence of neutrophils, therefore, is not necessarily a pathological occurrence.

Therefore, the NOEL is 220 mg/m^3 based on accumulation of alveolar macrophages in lung and the NOAEL is >980 mg/m^3 based on lack of systemic toxicity in males and females (ECHA) [Kl. score = 2].

Dermal

An OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study) was performed on New Zealand White rabbits. Five New Zealand White rabbits/sex/dose were topically administered hydrotreated light naphthenic oil six hours/day, three times a week for a period of 28 days at concentrations of 0, 200, 1000 or 2000 mg/kg body weight.

All animals were observed twice daily for mortality and signs of clinical toxicity and dermal irritation was scored daily (according to the Draize system). Body weights were measured and recorded for each rabbit at the end of the quarantine period, at weekly intervals during the study and prior to termination.

No mortality was observed in control animals or at any dose level tested. Soft feces was observed in some male and female rabbits in the control, mid-dose (1000 mg/kg) and high-dose (2000 mg/kg) dose groups. All female rabbits dosed at 2000 mg/kg hydrotreated light naphthenic oil appeared thin during the study period. Control males and females did not exhibit any dermal irritation while minimal irritation was observed in males and females dosed at 200 mg/kg hydrotreated light naphthenic oil. Slight to moderate irritation accompanied by very slight oedema and well-defined erythema was observed in males and females dosed at 1000 mg/kg. Moderate irritation with consistent erythema and oedema was seen in males and females dosed at 2000 mg/kg hydrotreated light naphthenic oil. A couple of females in the high-dose (2000 mg/kg) group also exhibited maximal erythema on day 20 of the study period. Body weight and body weight gain appeared to be normal in males in the control, low-dose (200 mg/kg), and mid-dose (1000 mg/kg) dose group. Mean body weights and body weight gain were lower (statistically significant) than control in the high-dose males and in the mid-dose (1000 mg/kg) and high-dose (2000 mg/kg) females. Most of the hematology parameters were found to be normal for males and females in all

dose groups. WBC counts in the low-dose (200 mg/kg) females were lower than those observed in control animals but were considered incidental and not treatment-related. Clinical chemistry parameters appeared to be normal in males and females in all dose groups. One female in the mid-dose (1000 mg/kg) dose group exhibited abnormally high Serum glutamic pyruvic transaminase (SGPT) and serum glutamic-oxaloacetic transaminase (SGOT) levels but this was considered incidental, and not treatment-related. Mean terminal body weights of mid-dose (1000 mg/kg) females and high-dose (2000 mg/kg) males and females were observed to be lower (statistically significant) than the corresponding control animals. Absolute left and right testis weights and relative right testis weights for the high-dose (2000 mg/kg) dose males were also found to be lower (statistically significant) than the corresponding controls. All other statistically significant differences in organ weights in both males and females were considered to be incidental and not treatment-related. Post-termination gross morphology examinations revealed dry, scaly, rough, fissured, crusted and/or thickened skin in animals in the high-dose (2000 mg/kg) group. Two high-dose (2000 mg/kg) males were also observed to have bilaterally small testes. Histopathological examinations revealed slight to moderate proliferative changes of the skin accompanied by increased granulopoeisis of the bone marrow in all male and female rabbits dosed with 2000 mg/kg API 83-12. Testes of 3 of 5 high-dose (2000 mg/kg) males were observed to have bilateral diffuse tubular hypoplasia (atrophy) accompanied by aspermatogenesis and atrophy of accessory sex organs. Systemic effects may be a secondary effect due to effects at primary site of application.

The systemic toxicity NOAEL for this 28-day dermal toxicity study in the rabbit is 1000 mg/kg, based on the lack of adverse systemic effects observed at this dose level (ECHA) [KI Score = 1].

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on CMW based on read-across from aluminium compounds are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on DPHP[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Petroleum industry modified OECD Guideline 471 (Bacterial Reverse Mutation Assay)	-	+	1	ECHA

*+, positive; -, negative
1 – based on read across to aluminium compounds.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed. Male and female mice (Strain CD-1) were given a single intraperitoneal injection of five different paraffin oils in corn oil vehicle at doses of 0, 1.0, 2.5 or 5.0 g/kg. Bone marrow cells were harvested at 24, 48 and 72 hours post-dosing. One animal did not survive to scheduled

sacrifice, but there were no gross signs of toxicity. The micronucleus frequency was significantly greater than the concurrent negative control in bone marrow cells of male mice given 5.0 g/kg at 48 hours post-dosing, but the negative control was unusually low in this instance, and therefore the positive result at 5 g/kg (5000 mg/kg) is not considered significant. The substance is not considered mutagenic (ECHA) [Kl. score = 1].

G. Carcinogenicity

Oral

No substance specific data exist (ECHA) (Kl score = 3).

Inhalation

No studies are available.

Dermal

Numerous lifetime dermal carcinogenicity studies have been carried out on lubricant base oils. A comprehensive review of these studies is not provided however, the results are summarized below.

Overall, these studies have shown that lubricant base oils that have been refined to a sufficient degree of severity, i.e., solvent-extraction and/or severe hydrotreatment do not normally induce skin cancer in mice. However, lubricant base oils that have not been sufficiently refined may be carcinogenic to the skin. The IP 346 test is used to determine whether the lubricant base oils have been sufficiently refined to avoid dermal carcinogenic hazard. The method measures the quantity of dimethyl sulfoxide (DMSO) extract which has been proved to correlate to the carcinogenic properties of the other lubricant base oils. Other lubricant base oils are classified for dermal carcinogenic hazard unless they have been shown to contain less than 3 wt% DMSO extractable material according to the IP 346 method.

In order to understand the effects of various types of refining processes (i.e., hydrotreatment, solvent extraction, combined solvent extraction and hydrotreatment) on carcinogenic potential, 94 lubricant base oils and related materials were evaluated in the mouse epidermal cancer bioassay these studies, male C3H mice, ca. 6-10 weeks of age, were randomly distributed into test groups of 40 or 50 animals. In early studies, mice were housed five per cage in suspended wire-mesh cages. In later studies, they were housed singly, in the same type of cages. The hair in the interscapular area was clipped once weekly to facilitate test material application. The test materials were applied by automatic pipette in either 37.5 microlitres aliquots twice a week or 25 microlitres aliquots three times a week. In early studies, the treatment continued until the animals died spontaneously or were sacrificed in a moribund state. In later studies, surviving mice were sacrificed after either 24 months of treatment or at the time at which grossly diagnosed squamous cell carcinomas were recorded. Animals were examined twice weekly for the appearance of dermal tumours. Each tumour in the treatment area was examined carefully and classified grossly. All grossly diagnosed tumours were examined microscopically after study termination.

Of the 94 samples tested for carcinogenic activity, 57 produced no tumour-bearing animals and the remaining 37 produced one or more. Among the groups containing tumour-bearing animals, seven had one, six had two, two had four and the remaining 22 had five or more. At least five tumour-bearing animals are required to differentiate statistically one of the treatment group responses from that of an equally sized negative control group (containing no tumour-bearing animals), Thus, responses were statistically significant in 22 of the 37 groups containing tumour-bearing animals. Overall, based on the refinement status of DPHP, the substance is considered carcinogenic via the dermal route (ECHA) [KI Score = 3].

H. Reproductive Toxicity

Oral

An OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test) was performed on Sprague Dawley rats.

A lubricant base oil (IP 346 < 3 wt%) was administered by gavage at a dose of 1000 mg/kg (bw) to a group of 12 male and 12 female Sprague-Dawley rats. Rats designated F0 animals were dosed for a minimum of 14 days prior to mating. Dosing was continued after mating until a total dosing period of 30 days had elapsed for males and until day 4 of lactation for females (39 days). The animals were observed twice daily for appearance, behaviour, morbidity and mortality. Males and females were also observed during dosing and for one hour thereafter. Male F0 body weights were recorded weekly. Female F0 body weights were also recorded weekly until evidence of mating was observed and then on gestation days 0, 7, 14 and 20 and on lactation days 1 and 4. Food consumption was also recorded for F0 (both sexes). Animals were paired on a 1:1 basis. Positive evidence of mating was confirmed either by the presence of sperm in a vaginal smear or a vaginal plug. The day when evidence of mating was identified was termed Day 0 of gestation.

The following fertility indices were calculated: Female mating index; Male mating index; Female fertility index; and Male fertility index. All females were allowed to deliver their young naturally and rear them to post-natal day 4. Females were observed twice daily during the period of expected parturition for initiation and completion of parturition and for signs of dystocia. After parturition, litters were sexed and examined for evidence of gross malformations, numbers of stillborn and live pups. Litters were examined daily, and each pup received a detailed physical examination on days 1 and 4 of lactation. All abnormalities were recorded. The live litter size and viability index were calculated. All surviving pups were necropsied on post-natal day 4. A complete gross examination was made on all animals at necropsy. Selected organs of parental animals were weighed, and a wide range of tissues were fixed for subsequent histopathological examination.

There were no clinical findings and growth rates and food consumption values were normal. Fertility indices and mating indices for males and females were both 100%. At necropsy, there were no consistent findings, and the animals were considered to be normal. Organ weights and histopathology were considered normal. The NOAEL for this study was ≥1000 mg/kg/day (ECHA) [KI Score = 1].

I. Developmental Toxicity

Dermal

There are no oral developmental toxicity studies of lubricant base oils with IP 346 > 3%. However, there is a dermal developmental toxicity study (OECD Guideline 414 - Prenatal Developmental Toxicity Study) of a distillate aromatic extract (DAE) from a heavy paraffinic vacuum distillate which can be used as a worst case basis to assess the developmental toxicity of lubricant base oils with IP 346 > 3 wt%.

In this study heavy paraffinic DAE (CAS No. 64742-04-7), 318 Isthmus Furfural Extract, was tested in a dermal study during gestation days 0 to 19 for developmental effects and maternal toxicity in the Sprague-Dawley rat.

Heavy paraffinic distillate furfural extract produced maternal, reproductive and foetal toxicity. Maternal toxicity was exhibited as vaginal discharge (dose-related), body weight decrease, reduction in thymus weight and increase in liver weight (125 mg/kg/day and higher) and aberrant haematology and serum chemistry (125 and/or 500 mg/kg/day). Evidence of potential reproductive effects was shown by an increased number of dams with resorptions and intrauterine death. DAE was developmentally toxic regardless of exposure duration as indicated by increased resorptions and decreased foetal body weights. Furthermore, when exposures were increased to 1000 mg/kg/day and given only during gestation days 10 through 12, cleft palate and ossification delays were observed. Cleft palate was considered to indicate a potential teratogenic effect of DAE (ECHA) [Kl. score = 1].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for DPHP follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The repeated dose NOAEL for heavy paraffinic distillate aromatic extract could not be identified but is less than 125 mg/kg/day when administered orally. 125 mg/kg/day is considered the NOAEL for purposes of developing a drinking water guideline. For reproduction, breeding and early post-natal developmental toxicity, the NOAEL is 1000 mg/kg-day. The NOAEL of 1000 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10

UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 10

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 125/1000 = 0.10 mg/kg-day.

It should be noted that the oral RfD of 0.1 mg/kg/day is in good agreement with an RfD of 0.1 mg/kg/day for EC9–EC10, >EC10–EC12 and >EC12–EC16 aliphatic fractions developed by the World Health Organization (WHO, 2008).

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.1 x 70 x 0.1)/2 = 0.3 mg/L

B. Cancer

DPHP was not carcinogenic to rats in chronic oral studies. Therefore, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

DPHP does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Details from studies on surrogate substances are provided below.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on DPHP.

Table 3: Acute Aquatic Toxicity Studies on DPHP

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-h LC_{50}	>100	2	ECHA
Daphnia magna	48-h EC_{50}	>10,000	2	ECHA
Pseudokirchneriella subcapitata	72-h NOEL	>100	2	ECHA

Chronic Studies

Fish:

Results of computer modelling to estimate aquatic chronic toxicity of other lubricant base oils in a 28-day freshwater fish study show no chronic toxicity to freshwater fish at or below its maximum attainable water solubility (ECHA) [KI Score = 3).

Invertebrates:

In a key semi-static 21-day long-term Daphnia magna toxicity test, 10 animals/loading were exposed to the Water Accommodated Fraction (WAF) of other lubricant base oil LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1, 10, 100 and 1000 mg/L. A NOEL was 10 mg/L based on reproduction but was attributed to a non-treatment related effect, the cause of which was unknown. Further testing would be required to clarify the consequences of exposure to a 100 mg/L WAF of the base oil (ECHA) [KI Score = 2].

In a supporting semi-static 21-day long-term Daphnia magna reproduction test, 10 animals/loading were exposed to the WAF of solvent-refined heavy paraffinic distillate (PSG 1860; CAS # 64742-04-7) at nominal concentrations of 0, 10 and 1000 mg/L. The EL_{50} was > 1000 mg/L and the NOEL was ≥ 1000 mg/L based on the lack of mortality or reproduction impairment (ECHA) [KI Score = 2].

In supporting semi-static 21-day long-term Daphnia magna reproduction test (OECD 211; KS = 2), 10 animals/loading were exposed to the WAFs of other lubricant base oils HVI 60, XHVI 4.0, HVI 65 and LVIN 38 (CAS #64742-53-6) at nominal concentrations of 1 and 1000 mg/L. The NOELs for other lubricant base oils HVI 60, XHVI 4.0 and HVI 65 were ≥ 1000 mg/L based on reproduction. The NOEL for LVIN 38 was ≥1 mg/L based on reproduction this substance was retested across a wider range of nominal concentrations and a NOEL of 10 mg/L was determined (ECHA) [KI Score = 1].

C. Terrestrial Toxicity

No data were available.

D. Calculation of PNEC

The PNEC calculations for DPHP follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. The lowest acute EC_{50} value was >100 mg/L. On the basis that the data consists of short-term studies for three trophic levels, an assessment factor of 100 has been applied to the lowest reported EC_{50} value of 100 mg/L. Therefore, the PNECwater is 1 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the substance is not expected to substantially partition to sediments. Nonetheless, a PNECsed was calculated using the equilibrium partitioning methodology. The PNECsed is 469 mg/kg sediment wet weight.

The calculations are as follows:

PNECsed = (Ksed-water/BDsed) x 1000 x PNECwater
= 3.2×10^4/1280 x 1000 x 1
= 2.5×10^4

Where:

Ksed-water = suspended matter-water partition coefficient (m3/m3)
BDsed = bulk density of sediment (kg/m3) = 1,280 [default]

Ksed-water = 0.8 + [(0.2 x Kpsed)/1000 x BDsolid]
= 0.8 + [(0.2 x 1.25×10^5/1000 x 1,280]
= 3.2×10^4

Where:
Kpsed = solid-water partition coefficient (L/kg).
BDsolid = bulk density of the solid phase (kg/m^3) = 2,400 [default]

Kpsed = Koc x foc
= 3.1×10^6 x 0.04
= 1.2×10^4

Where:

Koc = organic carbon normalized distribution coefficient (L/kg). The Koc was calculated as the midpoint of modelled Koc range and determined to be 3.1×10^6 L/kg.

foc = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the PNECsoil was calculated using the equilibrium partitioning method. The PNECsoil is $4x10^4$ mg/kg soil dry weight.

The calculations are as follows:

PNECsoil = (Kpsoil/BDsoil) x 1000 x PNECwater
= (0.06/1500) x 1000 x 0.3
= $4x10^4$

Where:

Kpsoil = soil-water partition coefficient (m3/m3)
BDsoil = bulk density of soil (kg/m3) = 1,500 [default]

Kpsoil = Koc x foc
= $3.1x10^6$ x 0.02
= $6.2x10^4$

Where:

Koc = organic carbon normalised distribution coefficient (L/kg). The Koc was calculated as the midpoint of modelled Koc range and determined to be $3.1x10^6$ L/kg.

Foc = fraction of organic carbon in soil = 0.02 [default].

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REAC Criteria methodology (DEWHA, 2009; ECHA, 2008).

DPHP is an organic substance that has been determined to be inherently biodegradable. Thus, it does not meet the screening criteria for persistence.

The estimated log Kow is equal to 8. There is clear experimental evidence that super-lipophilic substances (log Kow > 7.2) will not have a significant tendency to bioaccumulate (ECETOC, 2000).

Therefore, DPHP is considered to not meet the screening criterion for bioaccumulation.

DPHP is a low toxicity concern based on the results presented in Table 3. Thus, DPHP does not meet the screening criteria for toxicity.

Therefore, DPHP is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

May cause cancer via dermal exposure. H350

B. Labelling

Danger

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eye and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for DPHP.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking, and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

DPHP is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). Persistent organic pollutants. Response to UNEC/INC/ CEG-1. Annex 1, Document No. 41. Brussels, Belgium.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

WHO. (2008). Petroleum Products in Drinking-water Background document for development of WHO Guidelines for Drinking-water Quality. WHO/SDE/WSH/05.08/123.

DIUTAN (CAS NO. 595585-15-2)
DIUTAN GUM (CAS NO. 125005-87-0)

This dossier on diutan and diutan gum presents the most critical studies pertinent to the risk assessment of these substances in its use in coal seam gas extraction activities. Diutan (CAS No. 595585-15-2) can also be referred to as diutan gum (CAS No. 125005-87-0). This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained for diutan gum from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2R,3R,4S,5S)-2,3,4,5-tetrahydroxyhexanal (2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanal (2S,3S,4S,5R)-2,3,4,5-tetrahydroxy-6-oxohexanoic acid acetic acid calcium dihydride hydrate magnesium dihydride potassium hydride sodium hydride

CAS RN: 125005-87-0

Molecular formula: $C_{20}H_{46}CaKMgNaO_{21}$

Molecular weight: Not applicable as substance is a UVCB.

Synonyms: Diutan gum; S 657; S-657 Gum; GEOVIS XT; GEOVIS XTL; KELCO-CRETE DG

Chemical Name (IUPAC): D-glucuronic acid, polymer with 6-deoxy L-mannose and D-glucose, acetate, Ca Mg K Na salt

SMILES: Not applicable

CAS RN: 595585-15-2

Molecular formula: $(C_6H_{12}O_6.\ C_6H_{12}O_5.\ C_6H_{10}O_7)x.C_2H_4O_2.\ xCa.xK.xMg.xNa$

Molecular weight: Not applicable as substance is a UVCB.

Synonyms: Diutan; D-Glucurono-D-gluco-6-deoxy-L-mannan, acetate, calcium magnesium potassium sodium salt.

SMILES: Not applicable

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1:Overview of the Physico-chemical Properties of Diutan Gum (CAS No. 125005-87-0)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Off-white solid powder	1	ECHA
Melting Point	No melting point was determined. Test substance decomposed at >175°C.	2	ECHA

Property	Value	Klimisch score	Reference
Boiling Point	No data	-	-
Density	1430 Kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	~0.1 kPa @ 25°C	-	NICNAS, 2010
Partition Coefficient (log K_{ow})	-3.56 @ 20°C	2	ECHA
Water Solubility	40 g/L @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Diutan/diutan gum is readily biodegradable, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Biodegradation

A GLP-compliant study conducted in accordance with the OECD guideline was available. The test material (diutan gum) attained 95% degradation after 28 days and satisfied the 10-day window validation criterion, whereby 60% degradation must be attained within 10 days of the degradation rate exceeding 10%. The test material can therefore be considered to be readily biodegradable under strict terms and conditions of the OECD guideline 301B [Kl Score = 1] (ECHA).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

No experimental data are available for diutan/diutan gum. Based on the low experimentally determined log K_{ow} (-3.56) value, the substance has a low potential to adsorb to soil and will be highly mobile in soil.

D. Bioaccumulation

No experimental data are available for diutan/diutan gum. Based on the low log K_{ow} (-3.56), the potential for bioaccumulation is low.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Diutan has low acute toxicity by the oral and inhalation routes. It is not irritating to the skin and eyes and is not a skin sensitiser. No systemic effects were seen in repeated dose oral toxicity studies in rodents. The substance is not carcinogenic or genotoxic. No reproductive or developmental toxic effects were identified.

B. Toxicokinetics

A screening level toxicokinetic study was performed using male and female Sprague-Dawley rats. Radio labeled Gellan Gum mixed with corn oil was administered via gavage. Specific activity of formulated dose was checked by sample combustion and scintillation counting.

The study was performed in three stages. Stage 1 involved CO_2 collection from 1 male, 1 female. Stage 2 consisted of faeces collection and tissue distribution analysis from 4 males, 4 females. One female was excluded from the study due to abnormal findings at necropsy suggestive of maldosing. Stage 3 involved collection of blood levels from 4 males, 4 females.

Stage 1 results showed less than 0.55% of dosed radioactivity was expired in the form of $^{14}CO_2$. Stage 2 results indicated that females excreted 1.85 +/- 0.55% of dosed ^{14}C in urine, 86.79 +/- 3.08% in faeces. The Stage 3 results recorded low levels of radioactivity in the blood: mean peak blood radioactivity in both sexes was close to 3,000 DPM/mL blood, occurring around 5.5 hours post-dosing in males, 5.25 hours post-dosing in females.

The low levels of radioactivity recorded in tissues and blood samples and the high levels of radioactivity excretion in faeces suggest very little absorption from the gastrointestinal tract occurred following oral dosing. No potential for bioaccumulation was indicated by the study findings. Based on the close chemical similarity between gellan gum and diutan, it is reasonable to predict that a comparable pattern of non-absorption would be seen if diutan were to be similarly tested (ECHA) [Kl. score = 2].

C. Acute Toxicity

<u>Oral</u>

An acute Limit Test, in accord with USEPA test guideline USEPA 40 CFR 163.81-1 was performed. Six male and six female Sprague Dawley rats were administered 5,000 mg/kg in corn oil via gavage. Rats were weighed prior to dosing, then 7 and 14 days later and were observed 1, 2 and 4 hours post-dose, then daily up to 14 days after dosing. Gross pathology observations were made at necropsy. No evidence of toxicity was seen. A no observed effect level (NOEL) of 5,000 mg/kg was determined (ECHA) [Kl Score = 2].

<u>Inhalation</u>

A standard acute inhalation study was performed according to method USEPA 40 CFR 163.81-3. Five male and five female Sprague-Dawley rats were exposed whole body to substance dust for 4 hours in air at a measured test atmosphere of 0.316 mg/L (mean across sampling times). Particle size distribution (measured using Andersen plate sampler during the final 15 minutes of exposure): 100% < 10 microns, 28.9% ≤ 1.1 microns.

After 14 days post-exposure observation, all rats were terminated. Following gross pathology observations at necropsy, lungs and tracheal structures were collected into buffered formalin. Lungs and tracheal samples were also collected from a sample of rats taken at the time of animal delivery (pre-study) and from a supplementary non-exposed control group (additional to the air-exposed controls) at study termination.

No evidence of toxicity was seen after 4-hour exposure of rats to the test substance in a dust atmosphere (nominally 4.9 mg/L and measured at 0.316 mg/L). The difference between nominal and

measured concentrations may indicate that close to a maximum practicable concentration was achieved (ECHA) [KI Score = 2].

Dermal

No studies were available.

D. Irritation

Skin

A non-guideline dermal irritation study was performed on Dunkin-Hartley guinea pigs. The substance was applied in arachis oil at four different concentrations at separate sites on the clipped flanks: 5, 10, 25, 50%. Application sites were occluded for 24 hours and observed 1, 24 and 48 hours after dressing removal. Erythema and oedema scores at 50% concentration did not indicate test substance was irritating (ECHA) [KI Score = 2].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) was performed on albino rabbits. 100 mg substance was applied to one eye while the contralateral eye served as a control. Ocular reactions were observed at 24, 48 and 72 hours post-treatment. Cornea opacity, iris and conjunctivae scores were not indicative of irritation. Therefore, diutan is considered not irritating (ECHA) [KI Score = 2].

E. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) was performed on male Dunkin-Hartley guinea pigs. Intradermal induction was performed with 5% w/w in dried arachis oil. Topical (epicutaneous) induction was performed with 50% w/w in dried arachis oil. Topical challenge was performed with 25% and 10%, w/w in dried arachis oil. The test material produced a 0% (0/10) sensitisation rate and was determined as a non-sensitiser to guinea pig skin under the conditions of the test (ECHA) [KI score = 1].

F. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) was performed using the structural analogue K9A50: gellan gum (EC 275-117-5). Male and female Sprague-Dawley rats (20 each) were dosed at 3%, 4.5% and 6% nominally in the diet.

Mortality was checked twice daily; clinical signs were recorded once daily. Bodyweights and food consumption recorded pre-treatment and weekly during treatment. Opthalmoscopy checks (control and high-dose groups) were performed pre-treatment and prior to termination.

Haematology, blood chemistry and urinalysis were checked pre-treatment (health screen satellite group) and (together with faecal moisture content) in weeks 6 and 12 of treatment period (10 or 12 rats/sex/group).

Rats fed 6% gellan gum in diet for 13 weeks (corresponding to daily intakes ranging from 2.95 to 7.26 g/kg/day) showed no evidence of treatment related toxicity. It is reasonable to predict that a similar

pattern of low subchronic toxicity would be seen if diutan were to be tested in the same way (ECHA) [KI score = 2].

Inhalation

No adequate studies for human health risk assessment are available.

Dermal

No adequate studies for human health risk assessment are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on diutan are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Diutan[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-*	-*	2	ECHA

1 – Surrogate substance (Biozon - EC 476-190-8) evaluated
*+, positive; -, negative.

Diutan is not expected to induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed using the surrogate, Gellan gum (EC 275-117-5). Oral administration of gellan gum at up to 2 x 450 mg/kg produced no detectable increase in the frequency of micronucleated bone marrow cells in treated mice. It is predictable that diutan would give a similarly negative result if tested in the same manner.

H. Carcinogenicity

A mouse carcinogenicity study of the close chemical analogue gellan gum found that inclusion in diet at up to 3% had no significant toxic effect and did not increase the incidence of neoplastic (malignant or benign) or non-neoplastic lesions. The overall mean achieved intake of gellan gum at the highest tested level was calculated to be 4.9 g/kg/day (males) or 6.2 g/kg/day (females).

The open literature also includes a short summary of a rat carcinogenicity study which supports the conclusion that gellan gum is non-carcinogenic. The Joint FAO/WHO Expert Committee on Food Additives(1990) cites a carcinogenicity study in which rats first exposed to gellan gum in utero were then fed gellan gum at up to 5% in the diet for approximately 104 weeks.

No neoplastic or non-neoplastic changes were associated with gellan gum exposure.

The close chemical analogue gellan gum showed no evidence of carcinogenicity in rodent carcinogenicity studies. It is predictable that diutan would give a similarly negative result if tested in the same manner (ECHA) [KI Score = 2].

I. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed. Male and female Sprague Dawley rats were dosed with the diutan surrogate Gellan gum (EC 275-117-5) at 2.5, 3.8 and 5% in the diet per study guidelines.

Details on results (P0): No toxicologically significant effects were noted for general toxicity or reproductive function. No evidence of parental toxicity and no effect on reproductive performance seen at highest treatment level (5%).

Details on results (F1 and F2): No evidence of toxicity, no effect on reproductive performance and no effect on development of F1 rats seen at the highest treatment level (5%). No effects on F2 development seen at the highest treatment level (5%).

Administration of gellan gum to P and F1 rats at levels up to 5% in diet resulted in achieved adult intakes within the range 2.8-6.5 g/kg (males), 3.0-4.2 g/kg (females). No evidence of toxicity or adverse effects on reproductive performance or development was seen. Given the close similarity between gellan gum and diutan, it is reasonable to predict that diutan would show a similar lack of toxicity to reproduction (ECHA) [KI Score = 2].

J. Developmental Toxicity

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed with the diutan surrogate gellan gum (EC 275-117-5). The substance was administered via diet and restricted to the period of organogenesis (gestation dates 6-15). Females mated with one male of proven fertility; mating confirmed by presence of spermatozoa in vaginal lavage (designated gestation day 0).

Maternal Toxicity

No evidence of maternal toxicity was seen. Minor gross pathology findings at termination were considered unrelated to treatment. Pregnancy rate was at least 88% in all groups.

Embryotoxic / Teratogenic effects

The incidence of major malformations in test groups was no different from that among controls. Subcutaneous oedema and accompanying skin changes in 7 foetuses from one litter made the occurrence of minor external/visceral anomalies significantly raised at 3.8%. Cases of reduced ossification at 2.5% (mainly ribs) and 3.8% (mainly parietal bones) made group values significantly different from controls. Common skeletal (sternebrae 1-4) variants were significantly increased at 3.8%. None of the above minor anomalies/variants were seen in rats of the highest treatment group (5% in diet); it was concluded that they were not related to gellan gum exposure. It is reasonable to predict that diutan would show a similar lack of toxicity to development (ECHA) [KI score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diutan follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) was performed using the structural analogue K9A50: gellan gum (EC 275-117-5). The lowest NOAEL of 2.95 g/kg/day (i.e., 2,950 mg/kg bw/day) from this study was used to determine the oral RfD and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 2950/(10 x 10 x 1 x 1 x 1) = 2950/100 = 29.5 mg/kg bw/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (29.5 x 70 x 0.1)/2 = 103.25 mg/L

B. Cancer

The single carcinogenicity study by the oral route indicates diutan is not a carcinogen. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diutan does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Diutan is of low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 presents the results of acute aquatic toxicity studies on diutan/diutan gum.

Table 3: Acute Aquatic Toxicity Studies on Diutan Gum

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss (Rainbow Trout)	96-hour LC_{50}	100	1	ECHA
Daphnia magna	48-hour LC_{50}	> 100	1	ECHA
*Desmodesmus subspicatus (*previous name*: Scenedesmus subspicatus)*	72-hour EC_{50}	> 100 (growth rate and biomass)	1	ECHA

Chronic Studies

No data is available.

C. Terrestrial Toxicity

No data is available.

D. Calculation of PNEC

PNEC calculations for diutan acid follow the methodology discussed in DEWHA (2009).

PNEC water

Acute experimental results are available for three trophic levels (Table 3). Acute E(L)C50 values are available for fish (100 mg/L), invertebrates (> 100 mg/L) and algae (>100 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported value. The $PNEC_{water}$ for diutan is 1.0 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the low K_{ow} indicates that diutan is not expected to partition to sediments. Therefore, a the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.63 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
= (0.809/1280) x 1000 x 1.0
= 0.63 mg/kg sediment wet wt.

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
= 0.8 + [(0.2 x 0.035/1000 x 2400]
= 0.82 m^3/m^3

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
= 0.865 x 0.04
= 0.035 L/Kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for calculated from EPI Suite™ using the MCI is 0.865 L/kg .
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Moreover, diutan is biodegradable and due to its low K_{ow}, is not expected to partition to soil. Therefore, a $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.01 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
= (0.02/1500) x 1000 x 1.0
= 0.01 mg/kg soil dry weight

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
= 0.865 x 0.02
= 0.017 m^3/m^3

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for calculated from EPI Suite™ using the MCI is 0.865 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diutan/diutan gum is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Bioaccumulation of diutan/diutan gam is not expected to occur based on it log K_{ow} value of -3.56. Thus, diutan/diutan gum does not meet the screening criteria for bioaccumulation.

No chronic toxicity data is available. The E(L)C_{50} values from the acute aquatic toxicity studies on diutan/diutan gum are > 1 mg/L. Thus, diutan/diutan gum does not meet the criteria for toxicity.

Therefore, diutan/diutan gum is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

Not Classified

C. Pictogram

Not Classified

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If eye irritation persists, seek medical attention, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

No significant adverse health effects are expected to develop if only small amounts (less than a mouthful) are swallowed. Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas. Not expected to cause an environmental hazard as a result of its intended use, disposal or incineration.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid dust formation. Avoid conditions that generate airborne dust in handling, transfer and cleanup. Keep away from heat, flame sparks and other ignition sources. Static charge may cause flash fire. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Store in a roofed and well-ventilated area. Keep container tightly closed. Store away from heat and light.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

If handling generates dust levels which cause irritation, or results in personal exposure exceeding the Occupational Exposure Standard (OES) of 10 mg/m^3 (8 hr time-weighted average [TWA] reference period) for total inhalable dust, then suitable approved dust respirator should be used.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Although this product does not present a significant skin concern, minimise skin contamination by following good industrial practice. Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: This product does not cause significant eye irritation or eye toxicity requiring special protection. Where there is significant potential for eye contact, wear chemical goggles and have eye flushing equipment available.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diutan is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Joint FAO/WHO Expert Committee on Food Additives (1990). Toxicology Monograph 724 (Food Additive Series 28.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS. (2010). National Industrial Chemicals Notification and Assessment Scheme. Full Public Report. Diutan Gum https://www.industrialchemicals.gov.au/sites/default/files/SN20%20Public%20Report%20PDF.pdf

ALCOHOLS, C12-14, ETHOXYLATED

This dossier on ethoxylated C12-C14 alcohol presents the most critical studies pertinent to the risk assessment of alcohols, ethoxylated C12-C14 alcohol in its use in coal seam gas extraction activities. As very little information exists upon which to assess ethoxylated C12-C14 alcohol, this dossier is based on an assessment of a surrogate substance C12-15, ethoxylated alcohols CAS 68131-39-5. This approach is appropriate since the surrogate substance differs from the subject substance by only a single carbon molecule. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name: Alcohols, C12-14, ethoxylated

CAS RN: 84133-50-6

Molecular formula: (C2H4O)1-3(CH2)10-13C2H6O

Molecular weight: Not available

Synonyms: Alcohols, C12-14, ethoxylated

SMILES: Not available

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of Alcohols, C12-15, Ethoxylated (1 to 2.5 moles ethoxylated)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear liquid with a rancid odour*	2	ECHA
Melting Point	7.22°C	2	ECHA
Boiling Point	ca. 287°C	1	ECHA
Density	0.926 g/cm^3 @ 15.56°C	1	ECHA
Vapour Pressure	Negligible	-	ECHA
Partition coefficient (log K_{ow})	5.06* @ 25°C	2	ECHA
Water Solubility	7 – 63 mg/L @ 25°C	2	ECHA
Flash Point	165.56°C	2	ECHA
Auto flammability	235°C	2	ECHA
Viscosity	28.1 mPA s (dynamic) @ 20°C	2	ECHA

*Based on alcohols, C12-14, ethoxylated (1 to 2.5 EO) [CAS No. 68439-50-9]

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

Alcohols, C12-15, ethoxylated is readily biodegradable. It has a low potential for bioaccumulation and a moderate potential for absorption to soil and sediment.

B. Biodegradation

Alcohols, C12-15, ethoxylated is readily biodegradable. In an OECD 301B test, degradation was 72% in 28 days, but failed the 10-day window (ECHA) [Kl. score = 1].

An alcohol, C12-15, ethoxylated (7 EO) degraded 80 to 88% in 28 days when tested using a shake-flask CO_2-evolution test method (ECHA) [Kl. score = 2].

C. Environmental Distribution

Adsorption/desorption

No experimental data are available for alcohols, C12-15, ethoxylated. Using KOCWIN in EPISUITE™ (U.S. EPA, 2018), the estimated K_{oc} values for surrogates of alcohols, C12-15, ethoxylated are:

C12 linear alcohol, ethoxylated (2 EO): 279.5 L/kg (MCI) and 464.2 L/kg (K_{ow})

C15 linear alcohol, ethoxylated (2 EO): 1,691 L/kg (MCI) and 3,018 L/kg (K_{ow})

D. Bioaccumulation

The bioconcentration factor (BCF) values for alcohol ethoxylates in fathead minnows have been reported to range from <5 to 387.5 (Toll et al., 2000). The uptake rates varied from 330 to 1660 (L x kg/d) and elimination rates varied from 3.3 to 59 per day (Toll et al., 2000). The high concentrations in fish is thought to be prevented by an efficient biotransformation of the alcohol ethoxylates, leading to a high elimination rate.

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of alcohols, C12-15, ethoxylated is low by the oral and dermal routes. The skin irritation rabbit studies on alcohols, C12-15, ethoxylated have shown mixed results, but human patch studies on these alcohol ethoxylates do not support a skin irritant classification. Alcohols, C12-15, ethoxylated is expected to be irritating to the eyes of rabbits. Alcohols, C12-15, ethoxylated is not a skin sensitiser. Repeated dose toxicity studies on alcohol ethoxylates similar to alcohols, C12-15, ethoxylated in rats do not indicate any target organ effects. These alcohol ethoxylates are not genotoxic, carcinogenic, and have a low potential for reproductive and developmental toxicity.

B. Acute Toxicity

No acute toxicity studies are available on alcohols, C12-15, ethoxylated.

The oral LD_{50} in rats for $C_{12\text{-}15}AE_3$ is >5,000 mg/kg (ECHA) [Kl. score = 2]. The oral LD_{50} in rats for $C_{12\text{-}15}AE_7$ is 1,700 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}}$

$_{13}AE_{6.5}$ is 2,100 mg/kg (HERA, 2009) [Kl. score = 2]. The oral LD_{50} value in rats for $C_{12\text{-}15}AE_{11}$ is >2,000 mg/kg in males and between 1,000 and 2,000 mg/kg in females (HERA, 2009) [Kl. score = 2]. The oral LD_{50} values in rats for $C_{14\text{-}15}AE_{13}$ in two separate studies are 1,100 and 1,000 mg/kg (HERA, 2009) [Kl. score = 2]. The relative number of EO units, but not the carbon chain length, appears to influence acute oral toxicity (HERA, 2009).

An acute dermal LD_{50} values of >2,000 mg/kg were determined for $C_{12\text{-}14}AE_3$ and $C_{12\text{-}14}AE_6$ in two separate studies (HERA, 2009) [Kl. score = 2]. The acute dermal LD_{50} of $C_{12\text{-}15}AE_7$ is >2,000 mg/kg (HERA, 2009) [Kl. score = 2].

C. Irritation

Skin

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under occlusive conditions was considered irritating (ECHA) [Kl. score = 2].

Application of 0.5 mL isotridecanol, ethoxylated (3 EO) to the skin of rabbits for 4 hours under semi-occlusive conditions was not considered irritating (ECHA) [Kl. score = 2].

In a 24-hour human patch test, there was some short-lived redness in some individuals from the application of $C_{12\text{-}14}AE_3$, but there was no scaling or oedema in any subjects (HERA, 2009) [Kl. score = 2].

In a standard 4-hour human patch test, the irritation potential of $C_{12\text{-}15}AE_5$ and $C_{12\text{-}15}AE_5$ were compared to 20% sodium dodecyl sulfate (which is classified a skin irritant under GHS). The results showed that neither alcohol ethoxylate should be classified as a skin irritant (Basketter et al., 2004) [Kl. score = 2].

Eye

Most alcohol ethoxylates tested as the undiluted neat test material are moderately to severely irritating to the eyes of rabbits, with an eye irritation index (EII) ranging from >25 to 50 (HERA, 2009). The alcohol ethoxylates $C_{12\text{-}14}AE_3$, $C_{12\text{-}14}AE_6$, $C_{13}AE_6$, and $C_{12\text{-}14}AE_{10}$ were found to be moderately to severely irritating to the eyes of rabbits (HERA, 2009). In another study, $C_{12\text{-}15}AE_{11}$ was considered moderately to severely irritating to the eyes of rabbits (HERA, 2009).

Some alcohol ethoxylates were reported to be practically or minimally irritating to the eyes of rabbits with EII scores of 0.5 to 15. These alcohol ethoxylates include: $C_{12\text{-}15}AE_3$, $C_{14\text{-}15}AE_7$, $C_{12\text{-}14}AE_{15}$, $C_{14\text{-}15}AE_{18}$, and $C_{13}AE_{20}$ (HERA, 2009).

D. Sensitisation

No sensitisation studies are available on alcohols, C12-15, ethoxylated.

In a guinea pig maximisation test, $C_{12\text{-}13}AE_{<2.5}$ (CAS No. 66455-14-9) was not considered a skin sensitiser (ECHA) [Kl. score = 2].

In a guinea pig maximisation tests, $C_{12\text{-}15}AE_3$, $C_{12\text{-}15}AE_7$, and $C_{14\text{-}15}AE_7$ were not considered skin sensitisers (HERA, 2009) [Kl. scores = 2].

E. Repeated Dose Toxicity

Oral

Rats were given in their diet 0%, 0.0313%, 0.0625%, 0.125, 0.25, 0.5 or 1.0% $C_{12\text{-}15}AE_7$ for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 102 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were fed $C_{12\text{-}14}AE_7$ in the diet at concentrations of 0%, 0.0313%, 0.0625%, 0.125%, 0.25%, 0.5% and 1.0% for 90 days. The animals in the ≥0.25% groups showed significantly reduced body weight gain, which was associated with marked decreases in food and water consumption. Relative liver weights were significantly increased in the ≥0.5% male rats and ≥0.25% females. Histopathologic examination showed hepatocytic enlargement in the ≥0.125% groups, suggesting increased liver metabolism on the basis of increased alkaline phosphatase activity at the higher dose levels. The NOAEL was established at 0.0625% in the diet or 110 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female Wistar rats were given in their diet 0, 300, 1,000, 3,000 and 10,000 ppm $C_{14\text{-}15}AE_7$ for 90 days. There were no deaths during the study. Mean body weights and feed were lower in 10,000 ppm males and the 3,000 ppm females. Feed consumption was lower in the 10,000 ppm animals and the 3,000 ppm females. Relative liver weights were increased in the ≥3,000 ppm animals, and relative spleen weights were increased in the 10,000 ppm males. Clinical chemistry changes were noted in the 10,000 ppm group and consisted of significantly higher urea, chloride and potassium levels in males; significantly higher urea, chloride and cholesterol in females. Increased total leucocytes and lymphocytes were seen in the 10,000 ppm animals and in the 3,000 ppm males. The 10,000 ppm females showed lower numbers of neutrophils; mean cell volume and mean cell haemoglobin were identified in one or both sexes fed in the ≥3,000 ppm dose groups. In the 1,000 ppm females, there were minor, but statistically significant changes in the liver and kidney weights and plasma urea concentration; these effects were considered to be of no toxicological significance. Histopathologic examination showed no treatment-related effects at any dose level. The NOAEL for this study is 1,000 ppm in the diet, which corresponded to 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5, or 1% $C_{14\text{-}15}AE_7$ for 90 days. Body weights, food intake, organ weights, and hematology and clinical chemistry parameters were similar across groups. The NOAEL for this study is 1% in the diet, which corresponded to 700 and 785 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Rats were given in their diet 0, 0.1, 0.5 or 1% $C_{12\text{-}13}AE_{6.5}$ or $C_{14\text{-}15}AE_7$ for two years. Body weight gain was reduced in the 1% males and ≥0.5% females, which was likely due to the reduced food consumption in these animals. At study termination, organ to body weight ratios were increased in the ≥0.5% females (liver, kidney and brain), 1% females (heart), and

1% males (liver). A dose-related focal myocarditis was observed in males. While focal myocarditis is commonly observed in non-treated aging rats, the incidences in the treated animals were higher than in the controls. The NOAEL was established at 0.1% or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Male and female CR rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. Relative liver, kidney, heart and thyroid/parathyroid gland weights were increased in the 1% dietary group at study termination. Histopathological examination showed a dose-related increase in the incidence of focal myocarditis at the 12-month time point, but not at the end of the study at two years. The NOAEL for this study was considered to be 0.5% in the diet, which corresponded to 162 and 190 mg/kg-day for males and females, respectively (HERA, 2009) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No adequate studies are available.

F. Genotoxicity

In *Vitro* Studies

The genotoxicity studies conducted on alcohol ethoxylates are reviewed in HERA (2009). The results of few of the *in vitro* studies on similar alcohol ethoxylates to alcohols, C12-15, ethoxylated are presented below in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Selected Alcohol Ethoxylates

Test Substance	Test System	Results*		Klimisch Score	References
		-S9	+S9		
$C_{14\text{-}15}AE_7$	Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	HERA, 2009
$C_{14}AE_{12}$	Chromosomal aberrations (CHO cells)	-	-	2	HERA, 2009

*+, positive; -, negative

In V*ivo* Studies

In two separate studies, CD-1 mice were given an intraperitoneal dose of 0, 50 or 100 mg/kg $C_{12\text{-}15}AE_3$ or $C_{12\text{-}14}AE_9$. There were no increases in the frequency of micronuclei in the bone marrow cells (Talmage, 1994) [Kl. score = 2].

Male and female Tunstall rats were given a single oral gavage dose of 0, 250, 500 or 1,000 mg/kg $C_{14\text{-}15}AE_7$. There were no increases in chromosomal aberrations in the bone marrow cells (HERA, 2009 [Kl. score = 2].

G. Carcinogenicity

No studies are available on alcohols, C12-15, ethoxylated.

Male and female Sprague-Dawley rats were given in their diet $C_{12\text{-}13}AE_{6.5}$ in the diet at doses up to 1% (500 mg/kg-day). Reduced food consumption was noted at the higher dose levels (*i.e.*, 0.5 and 1% for females and 1% for males), resulting in a lower body weight gain compared to the control group. No treatment-related histopathology was found and no increase in tumour incidence was observed (HERA, 2009) [Kl. score = 2].

Male and female Charles River rats were given in their diet 0, 0.1, 0.5 or 1% $C_{14\text{-}15}AE_7$ for two years. There were no treatment-related changes in general behaviour and appearance. The survival rate of the test animals was comparable if not better than the controls. Body weights of the 0.5% females and the 1% males and females had significantly lower weight gains than the control. There were no treatment-related effects on organ weights and tumour incidence (HERA, 2009) [Kl. score = 2].

Male and female Sprague-Dawley rats were given in their diet $C_{14\text{-}15}AE_7$ at 0.1, 0.5 and 1% for two years. A treatment-related body weight depression was observed in females at the two highest treatment levels and in males at the 1% dose level, probably due to the poor palatability of the diet. There was no evidence for any carcinogenic activity (HERA, 2009) [Kl. score = 2].

H. Reproductive Toxicity

No studies are available on alcohols, C12-15, ethoxylated.

CD rats were given in their diet 0, 0.05, 0.1 or 0.5% (approximately 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$ in a two-generation reproductive toxicity study. There were no treatment related effects in the parents or pups on general behaviour, appearance or survival. At 0.5%, there was reduced weight gain in both the parental animals and the pups compared to the controls. Fertility was unaffected by treatment. The NOAEL for reproductive toxicity is 0.5% in the diet, which corresponds to 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

In a two-generation developmental and teratogenicity study, CD rats were given in their diet 0, 0.05, 0.1 or 0.5% $C_{14\text{-}15}AE_7$ (approximately 0, 25, 50 or 250 mg/kg-day). Three of the treated groups were given the test substance continuously throughout the study; in the other three groups the females received the test substance on GD 6-15 and the males were untreated. None of the deaths of parental rats during the study was considered to be compound-related. There were no treatment-related changes in behaviour or appearance in the parental rats or pups. Slightly lower body weight gain was noted in the 0.5% continuously treated females. Food consumption was similar for control and treated rats. Fertility, gestation and viability indices were similar across groups. The average 21-day body weights for the 0.5% continuous treated pups were significantly lower than that of the control. Relative liver weights of the 0.5% continuously treated F_1 parental animals were increased at the 91-day sacrifice; relative liver weights of the 0.5% continuously treated males were also increased at the 60-day and caesarean section sacrifices. There were no treatment-related histopathological lesions in any of the tissues from the F_0 and F_1 generations. The NOAEL for reproductive toxicity is 0.5% in the diet or 250 mg/kg-day (HERA, 2009) [Kl. score = 2].

I. Developmental Toxicity

No studies are available on alcohols, C12-15, ethoxylated.

In a two-generation reproductive toxicity study, Charles River rats were given in their diet 0, 0.05, 0.1 or 0.5% (about 0, 25, 50 or 250 mg/kg-day) $C_{12}AE_6$. General behaviour, appearance and survival were unaffected by treatment. At the 0.5% dose level, adults and pups gained less weight than the control rats. In the 0.5% dose group, there was a statistical increase in embryo lethality and soft tissue anomalies and at the 0.1% there was a statistical decrease in mean foetal liver weight. Neither of these effects was considered to be treatment-related by the authors as they showed no dose response characteristics. The NOAEL for maternal toxicity is 50 mg/kg-day. The NOAEL for developmental and teratogenicity is 0.1% in the diet or 50 mg/kg-day (HERA, 2009) [Kl. score = 2].

Pregnant rabbits were given by oral gavage 0, 50, 100 or 200 mg/kg $C_{12}AE$ from gestational days 2 to 16. Nine control rabbits and 31 treated rabbits died during the study. Surviving rabbits at the 200 mg/kg dose group generally showed slight losses of body weight. At 100 and 200 mg/kg, ataxia and a slight decrease in body weight was observed in the pregnant animals. In seven treated and two control rabbits, early deliveries were recorded. There were no treatment-related effects on corpora lutea, implantations, number of live foetuses and spontaneous abortions. The NOAEL for maternal toxicity is 50 mg/kg-day; the NOAEL for developmental toxicity is 200 mg/kg-day (HERA, 2009) [Kl. score = 2].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for alcohols, C12-15, ethoxylated follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

<u>Oral</u>

Two-year dietary studies in rats have been conducted on alcohol ethoxylates $C_{12-13}AE_{6.5}$ and $C_{14-15}AE_7$ (HERA, 2009). The lowest NOAEL from these studies is 50 mg/kg-day based on increased organ weights. The NOAEL of 50 mg/kg-day will be used to derive an oral reference dose and drinking water guidance value for alcohols, C12-15, ethoxylated.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 50/100 = <u>0.5 mg/kg-day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.5 x 70 x 0.1)/2 = 1.8 mg/L

B. Cancer

Several alcohol ethoxylates similar to alcohols, C12-16, ethoxylated were not carcinogenic to rats in a two-year dietary study. Thus, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Alcohols, C12-15, ethoxylated does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Alcohol, C12-15, ethoxylated has moderate chronic toxicity concern to aquatic life.

B. Aquatic Toxicity

In developing a water quality guideline for alcohol ethoxylates (ANZECC & ARMCANZ, 2000), the toxicity data was normalised for a specific alkyl chain length or a specific number of ethoxylate (EO) groups. The NOECs listed below were normalised to an alkyl chain length of C13.3 and EO of 8.2.

Freshwater fish: 2 species, 720 to 1,500 mg/L.

Freshwater crustaceans: 2 species, 590 to 860 mg/L.

Freshwater rotifers: 1 species, *Brachionus calyciflorus*, 1,300 mg/L.

Freshwater algae, diatoms and blue-green algae: 6 species, 200 to 8,700 mg/L.

Freshwater mesocosms: 4 NOEC data for multiple species tests were 80, 80, 320 and 330 mg/L, although replication was insufficient to meet OECD (1992) requirements. Normalised data were 380, 380, 320 and 1,520 mg/L.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

PNEC water

The ANZECC water quality guideline (2000) for freshwater is: "A high reliability trigger value of 140 mg/L was derived for AE (normalised data) using the statistical distribution method with 95% protection."

For the purposes of calculating the PNEC values for sediment and soil, the $PNEC_{water}$ will be 0.14 mg/L.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ values are 0.9 to 5.6 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (9.28/1500) \times 1000 \times 0.14$
$= 0.87$

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (60.36/1500) \times 1000 \times 0.14$
$= 5.63$

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 464 \times 0.02$
$= 9.28$

$Kp_{soil} = K_{oc} \times f_{oc}$
$= 3,018 \times 0.02$
$= 60.36$

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} values for alcohols, C12-15, ethoxylated based on K_{ow} values range from 464 to 3,018 L/kg (see section 3 C.).
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Alcohols, C12-15, ethoxylated is readily biodegradable and thus does not meet the screening criteria for persistence.

The BCFs in fish for ethoxylated alcohols (which includes alcohols, C12-15, ethoxylated) have been reported to range from <5 to 387.5. Thus, alcohols, C12-15, ethoxylated does not meet the screening criteria for bioaccumulation.

The chronic NOEC values for alcohols ethoxylates are >0.1 mg/L. Thus, alcohols, C12-15, ethoxylated do not meet the criteria for toxicity.

Thus, alcohols, C12-15, ethoxylated is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]

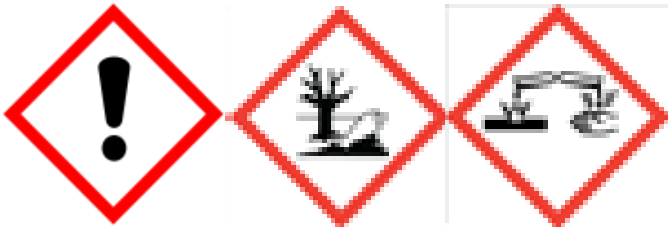
Eye Irritant Category 2

Aquatic Chronic Toxicity Category 3

B. Labelling

Warning

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

<u>Eye Contact</u>

Rinse immediately with plenty of running water. If easy to do, remove contact lenses. Get medical attention.

Skin Contact

Wash with soap and water. Get medical attention if symptoms occur.

Inhalation

Treat symptomatically. Move to fresh air. Get medical attention.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. Seek medical attention.

B. Fire Fighting Information

Extinguishing Media

Water spray, dry chemical, foam. Do not use water jet.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon oxides.

Special Protective Equipment for Firefighters

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

C. Accidental Release Measures

Personal Precautions

Wear appropriate personal protective equipment. Do not breath mist or aerosol.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Absorb spill with inert absorbent material, then place in a container for chemical waste.

D. Storage And Handling

General Handling

Protect against moisture. Shut containers immediately after taking product because product takes up the humidity of air. No special precautions are necessary beyond normal good hygiene practices.

Other Handling Precautions

Wash hands thoroughly after handling. Avoid breathing mists or aerosols.

Storage

Keep container closed.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for the substance.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Wear respiratory protection if ventilation is inadequate.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Chemical safety goggles.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Isotridecanol, ethoxylated is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZECC & ARMCANZ (2000). Australian and New Zealand guidelines for fresh and marine water quality. National Water Quality Management Strategy Paper No 4, Australian and New Zealand Environment and Conservation Council & Agriculture and Resource Management Council of Australia and New Zealand, Canberra, Australia.

Basketter, D.A., York, M., McFadden, J.P., and Robinson, M.K. (2004). Determination of skin irritation potential in the human 4-h patch test. Contact Dermatitis 51: 1-4.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Human and Environmental Risk Assessment (HERA) on Ingredients of Household Cleaning Products: Alcohol Ethoxylates (2009), http://www.heraproject.com.

OECD (1992). Report of the OECD workshop on extrapolation of laboratory aquatic toxicity data to the real environment. OECD Environment Monographs No. 59, Organisation for Economic Co-operation and Development, Paris.

Talmage, S.S. (1994). Environmental and Human Safety of Major Surfactants – Alcohol Ethoxylates and Alkylphenol Ethoxylates, pp. 35, The Soap and Detergent Association, Lewis Publishers, Boca Raton, Florida.

Toll, J., Haller, M., Labee, E., Verweij, M., and Sijm, D.T.H.M. (2000). Toxicology and Chemistry, 19 646–653.

U.S. Environmental Protection Agency [EPA] (2018). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of9Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

ETHOXYLATED OLEIC ACID

This dossier on ethoxylated oleic acid presents the most critical studies pertinent to the risk assessment of this substance in its use in drilling muds. As there is limited data on ethoxylated oleic acid, data from ethoxylated decanol (CAS RN 26183-52-8) will be used to further assess ethoxylated oleic acid. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-(decyloxy)ethan-1-ol

CAS RN: 26183-52-8

Molecular formula: not applicable, UVCB

Molecular weight: 130.23g/mol

Synonyms: 2-(Decyloxy)decanol, Deceth-4, Ethylene glycol monodecyl ether, Emulphogene DA 630, 2-(decyloxy)ethan-1-ol, Decyl alcohol, ethoxylated, Decanol, 2-(decyloxy)- , 2-(Decyloxy)decanol

2 PHYSICAL AND CHEMICAL PROPERTIES

Key physical and chemical properties for the substance are shown in Table 1.

Table 1 Overview of the Physico-chemical Properties of Ethoxylated Decanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Clear and colourless liquid	2	ECHA
Melting Point (101 kPa)	-27°C	1	ECHA
Boiling Point (101 kPa)	224°C	1	ECHA
Density (25°C)	0.88 g/cm³	2	ECHA
Vapor Pressure (kPa @ 20°C)	0.08	2	ECHA
Partition Coefficient (log K_{ow})	4.9	2	ECHA
Water Solubility (µg/L at 25°C, pH = 6-7)	82	2	ECHA
Flash Point @ 101.3 kPa	118.7°C	2	ECHA
Auto flammability (101,325 Pa)	220°C	1	ECHA
Viscosity (mm²/s @ 25°C)	13.911	2	ECHA

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

Ethoxylated decanol is readily biodegradable. It is not expected to bioaccumulate and decanol has a low tendency to bind to soil or sediment.

B. Biodegradation

An OECD Guideline 301 B (Ready Biodegradability: CO2 Evolution Test) was performed. Decanol, ethoxylated (6 EO) was tested for ready biodegradation according to OECD 301B. The degradation of the test item was 83% within 28 days (after acidification). The biodegradation of the test item reached the criterion for ready biodegradation (ECHA) [Kl. score = 1].

C. Environmental Distribution

Adsorption/desorption

Due to the specificity of the work carried out for alcohol ethoxylates, the lowest resulting Koc value based on modelling are used for further assessment is 1057 L/kg (at 20°C), indicating low mobility in soil (ECHA) [Kl Score = 2].

Bioaccumulation

A BCF of 237 L/kg was determined using the fathead minnow (ECHA) [Kl Score = 2].

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Ethoxylated decanol has low acute toxicity by the oral route and limited acute toxicity by the dermal route. No data were available for the inhalation route. It is not a skin and eye irritant nor is it a skin sensitiser. Repeated exposure studies in rodents caused limited toxicity. No data were available to evaluate carcinogenic effects although the lack of mutagenic effects suggests the substance is not a carcinogen. Ethoxylated decanol is not expected to have an effect on reproduction based on findings in animals from similar compounds. No developmental toxicity was seen in animals exposed to ethoxylated decanol by the oral, dermal or inhalation routes.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) study was performed on male/female Sprague-Dawley rats. Substance was administered via oral: gavage at a dose of 5,050 mg/kg bw. The LD_{50} > 5,050 mg/kg bw (ECHA) [Kl Score = 1].

Inhalation

An OECD Guideline 403 (Acute Inhalation Toxicity) study was performed on male/female Sprague-Dawley rats. The LC_{50} was determined to be > 1,600 mg/m³ air (ECHA) [Kl Score = 2].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) study was performed on male/female Wistar rats. The LD_{50} of > 2,000 mg/kg bw was determined (ECHA) [KI Score = 2].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was performed on New Zealand White rabbits. Very slight erythema was present at each observation through 24 hours in three animals. Oedema was not observed at any time throughout the study. Reported skin irritation results for the test animals indicate the substance is not an dermal irritant (ECHA) [KI Score = 2].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) was conducted using New Zealand White rabbits. Cornea opacity scores, iris score, conjunctivae score, and chemosis scores indicated that the substance was not irritating to the eye (ECHA) [KI Score = 2].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) was performed on Dunkin-Hartley guinea pigs.

A study was performed to assess the contact sensitisation potential of the test material in the albino guinea pig. Ten test and five control animals were used for the main study. Based on the results of sighting test, the concentration of the test material for the induction and challenge phases were selected as follows:

- Intradermal Induction: 1% w/v in arachis oil
- Topical Induction: undiluted as supplied
- Topical Challenge: 50% and 25% v/v in arachis oil

The test material produced a 0% (0/10) sensitisation rate and was classified as a NON-SENSITISER to guinea pig skin (ECHA) [KI Score = 1].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents) was performed on male and female Wistar rats. The oral repeated dose toxicity of the target substance was estimated based on an adequate and reliable subchronic oral toxicity key study performed with a structural analogue source substance. Daily oral exposure of male and female rats via the diet for 90 consecutive days to the test substance did not result in any toxicologically relevant effects. The NOAEL was determined to be > 500 mg/kg bw/day, corresponding to the highest dose tested. The result of the key study is further supported by additional (supporting) studies of various structural analogue source substances. Therefore, a systemic NOAEL after oral exposure for the target substance of > 500 mg/kg bw/day is established. The differences in molecular structure between the target and the source

substances are unlikely to lead to differences in oral repeated dose toxicity (ECHA) [Kl. score = 2].

Inhalation

No inhalation repeat dose data were available.

Dermal

No dermal repeat dose data were available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on ethoxylated decanol are presented in Table 3.

Table 3 *In Vitro* Genotoxicity Studies on Ethoxylated oleic acid[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains) OECD Guideline 471 (Bacterial Reverse Mutation Assay)**	-	-	2	ECHA

*+, positive; -, negative

** Neither E.coli WP2 strains nor S. typhimurium TA102 were used

1 – Data from ethoxylated decanol used (CAS RN 26183-52-8) as surrogate for ethoxylated oleic acid.

In Vivo Studies

An OECD Guideline 475 (Mammalian Bone Marrow Chromosome Aberration Test) was performed on male and female Sprague-Dawley rats. Rats were administered single doses of 450, 900 and 1500 mg/kg bw/day. Post euthanasia, femoral bone marrow smears were prepared. No chromosomal aberrations were noted. Therefore, the substance is considered to be non-mutagenic in vivo (ECHA) [Kl Score = 2].

G. Carcinogenicity

No studies are available.

H. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed on male/female Fischer 344 rats. Animals were treated dermally with doses of 1, 10 and 25% (w/v) to shaved dorsal region. The reproductive toxicity of the target substance is estimated based on an adequate and reliable two-generation reproductive toxicity study of a structural analogue source substance with subsequent detailed examination of foetuses. Dermal treatment of pregnant rats with the test substance at doses of 10, 100 and 250 mg/kg bw/day resulted in no maternal toxicity and hence a dermal NOAEL for maternal systemic toxicity of >/= 250 mg/kg bw/day. The NOAEL for reproductive toxicity, based on

observations in the P0, F1 and F2 generations was determined to be 250 mg/kg/day [Kl. score = 2].

I. Developmental Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed on male/female Fischer 344 rats. Animals were treated dermally with doses of 1, 10 and 25% (w/v) to shaved dorsal region. The developmental toxicity of the target substance is estimated based on an adequate and reliable two-generation reproductive toxicity study of a structural analogue source substance with subsequent detailed examination of foetuses. Dermal treatment of pregnant rats with the test substance at doses of 10, 100 and 250 mg/kg bw/day resulted in no maternal toxicity and hence a dermal NOAEL for maternal systemic toxicity of >/= 250 mg/kg bw/day. Foetal abnormalities observed include malformations of eyes and front as well as hind limbs. All developmental effects were due to spontaneous occurrence and were considered not to be treatment-related. The dermal developmental NOAEL was thus determined to be >/= 250 mg/kg bw/day. No developmental toxicity is therefore expected for the target substance. As explained in the category justification, the differences in molecular structure between the target and the source substances are unlikely to lead to differences in the developmental toxicity and teratogenicity.

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ethoxylated oleic acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

Non-Cancer

Oral

Two-year chronic studies have been conducted in rats given dermal doses of ethoxylated decanol. The lowest NOAEL from these studies is 50 mg/kg-day, based on reduced body weight and clinical signs in rats dosed with 150 and 500 mg/kg-day ethoxylated decanol. The NOAEL of 50 mg/kg-day will be used for determining the oral Reference Dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UFr (route to route variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 50/(10 x 10 x 10 x 1 x 1 x 1) = 50/1000 = 0.05 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (0.25 x 70 x 0.1)/2 = 0.875 mg/L

Cancer

Ethoxylated decanol was not carcinogenic to rats in chronic oral studies. Therefore, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ethoxylated decanol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ethoxylated oleic acid is moderately toxic to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 4 lists the results of acute aquatic toxicity studies conducted on ethoxylated oleic acid.

Table 4 Acute Aquatic Toxicity Studies on Ethoxylated oleic acid

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Cyprinus carpio and Danio rerio	96-hour LC_{50}	1.2	1	ECHA
Daphnia magna	48-hour EC_{50}	0.39	2	ECHA
Desmodesmus subspicatus	72-hour EC_{50}	1.4 (biomass) 1.8 (growth rate)	2	ECHA

Chronic Studies

No chronic test data were sufficient to derive meaningful toxicity values.

C. Terrestrial Toxicity

In an acute toxicity test according to OECD 207 no effect on earth worm *Eisenia fetida* was observed up to the highest test item concentration of 1,000 mg/kg soil dw. Therefore, the NOEL is determined to be >1,000 mg/kg dw (ECHA) [KI Score = 2].

D. Calculation of PNEC

The PNEC calculations for ethoxylated oleic acid follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute EC_{50} values are available for fish, invertebrates and plants. On the basis that the data consists of short-term studies from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported EC_{50} value of 0.39 mg/L for invertebrates. The $PNEC_{water}$ is 0.39 µg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the experimentally derived log Koc is 3. Given the relatively low log Koc value, a $PNEC_{sed}$ was not calculated.

PNEC soil

There is only a single acute toxicity study on terrestrial receptors (i.e., NOAEL >1000 mg/kg soil). Given the limited data for the soil compartment, an assessment factor of 1000 was applied to derive a $PNEC_{soil}$ of 1 mg/kg dw.

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ethoxylated oleic acid is readily biodegradable; thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 4.93, ethoxylated oleic acid does not meet the screening criteria for bioaccumulation.

The aquatic toxicity studies indicate toxicity >0.1 mg/L. Thus, ethoxylated oleic acid does not meet the screening criteria for toxicity.

Therefore, ethoxylated oleic acid is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

Causes serious eye irritation. H319.

B. Labelling

Warning

C. Pictogram



10 SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapor. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ammonium chloride.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapor cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

The substance is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCE

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

GELATINS

This dossier on gelatins presents the most critical studies pertinent to the risk assessment of gelatins in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Gelatins

CAS RN: 9000-70-8

Molecular formula: Not applicable as substance is a UVCB whose specific chemical composition is dependent on formulation processes.

Molecular weight: Depending on the specific commercial use, the molecular weight can range from 72 to 132 kDaltons (i.e., 72,000 to 132,000 g/mol) (Farrugia et. al., 1998)

Synonyms: None identified.

SMILES: Not applicable.

II. PHYSICAL AND CHEMICAL PROPERTIES

Gelatin is a white to yellow, translucent powder. It is hydrolysed and partially degraded collagen obtained by acid, alkaline or enzymatic hydrolysis. It is a polypeptide. Depending on the source of collagen and the method of its manufacturing process of recovery from collagen, gelatin contains an average of the following amino acids: glycine 21%, proline 12%, hypoproline 12%, glutamic acid 10%, alanine 9%, arginine 8%, aspartic acid 6%, lysine 4%, serine 4%, leucine 3%, valine 2, phenylalanine 2%, threonine 2%, isoleucine 1%, hydroxylysine 1%, histidine <1% and tyrosine <0.5% (Gorgieva and Kokol, 2011).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Gelatins are readily biodegradable; they are not expected to bioaccumulate or adsorb to soil.

B. Biodegradation

As a natural polymer, gelatin is expected to be readily biodegradable by most proteases when environmental conditions are adequate. While high molecular weight polymer degradation rates are generally thought to be low, the biopolymeric nature of gelatin in a variety of cross-linked forms appears to result in rapid biodegradation (e.g., 3-10 days) in the environment (Patel et. al., 2000).

Gelatin, as a rapidly biodegradable protein, is a rich source of amino acids and other nutrients such as nitrogen and carbon for bacteria and fungi. The increased bioavailability of nutrients could lead to a significant increase in biological oxygen demand (BOD) as a result of degradation of gelatin and the stimulated growth of microorganisms. High BOD will deplete local dissolved oxygen concentrations

when gelatin or its breakdown products are released into the aquatic environment in sufficient quantities relative to the volume of the receiving water body. This depletion of oxygen has the potential to place significant stress on some organisms within the aquatic environment (DoEE, 2017).

C. Environmental Distribution

Given the hydrophilic nature of gelatin it is unlikely that this biopolymer would adsorb to the soil or sediment.

D. Bioaccumulation

The potential for bioaccumulation is low. Based on the biological properties and the environmental fate of gelatin, especially the rapid biodegradation, prolonged exposure of aquatic organisms to the biopolymer will be highly unlikely (DoEE, 2017).

IV. HUMAN HEALTH HAZARD ASSESSMENT

There is no data on the human health hazard for this substance. However, based on its biopolymeric nature and uses in foods and medicines, the human health toxicity concern is expected to be very low.

NICNAS has assessed gelatin in an IMAP Tier 1 assessment and it was concluded that it poses no unreasonable risk to the environment[1]. In addition, based on an assessment of human health and environmental hazards, NICNAS also identified gelatin as a chemical of low concern to the environment (NICNAS, 2017 and DoEE, 2017). Chemicals of low concern are unlikely to have adverse environmental effects or be a concern to human health if they are released to the environment from coal seam gas operations.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference and drinking water guidance values have not been derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Gelatin does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no aquatic toxicity studies on gelatin. However, it is expected to have low concern for aquatic toxicity since any gelatin released into aquatic ecosystems will be rapidly degraded by microorganisms through enzymatic digestion to the individual amino acids or short peptides. If sufficient quantities of gelatin were abruptly released into a water body, this could cause temporary changes in water quality for local organisms, such as reduced dissolved oxygen concentrations (DoEE, 2017).

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9000-70-8%2C+

B. Aquatic Toxicity

No aquatic toxicity data was available.

C. Terrestrial Toxicity

No relevant studies were available.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Gelatins are readily biodegradable; thus, it does not meet the screening criteria for persistence.

The rapid degradation and expected lability to enzymatic degradation suggests gelatins will not meet the screening criteria for bioaccumulation.

There are no aquatic toxicity studies on gelatins. It is expected to have low concern for aquatic toxicity because of its bio-composition (e.g., various amino acids and crosslinked substituents) and rapid degradation rates in the environment. Thus, gelatin does not meet the screening criteria for toxicity.

The overall conclusion is that gelatin is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

Based on the low concern of this substance, and according to the majority of notifications provided by companies to ECHA under the Classification, Labelling and Packaging of Substances and Mixtures Regulation No 1272/2008, no hazards have been classified.

X. SAFETY AND HANDLING

Based on the low concern status of this substance, no specific safety or handling precautions are relevant.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy (DoEE). (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Farrugia, C.A., Farrugia, I.V. and Groves, M.J. (1998). Comparison of the Molecular Weight Distribution of Gelatin Fractions by Size-exclusion Chromatography and Light Scattering. Pharm. Pharmacol. Commun. 1998, 4: 559-562

Gorgieva, S, and Kokol V. (2011). 'Collagen- vs. Gelatine-Based Biomaterials and Their Biocompatibility: Review and Perspectives', in: Pignatello R (ed) Biomaterials applications for nanomedicine, INTECH, retrieved from http://www.intechopen.com/books/biomaterials-applications-for-nanomedicine.

Klimisch, H. J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol Pharmacol. 25:1-5.

NICNAS. (2017). Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra

Patel, Rajaram dattu, Dalev, P.G., and Mark, J.E. (2000). Biodegradation of chemically modified gelatin films in lake and river waters. Journal of Applied Polymer Science 76(1):29 – 37

ISOPROPANOL

This dossier on isopropanol presents the most critical studies pertinent to the risk assessment of isopropanol in its use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Propan-2-ol

CAS RN: 67-63-0

Molecular formula: C_3H_8O

Molecular weight: 60.1 g/mol

Synonyms: Isopropanol, isopropyl alcohol, 2-propanol, *sec*-propyl alcohol, dimethylcarbinol

SMILES: CC(C)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Isopropanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	2	ECHA
Melting Point	-88.5°C; -89.5°C[1]	2	ECHA
Boiling Point	82.5°C; 82.3°C @ 101.3 kPa	2	ECHA
Density	800 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	4,400 Pa @ 20°C; 6,002 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	0.05 @ 25°C	2	ECHA
Water Solubility	Miscible	2	ECHA
Viscosity	2.038 mPa s @ 25°C	2	ECHA

[1] No information on the atmospheric pressure reported.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Isopropanol is readily biodegradable. It is not expected to bioaccumulate. Isopropanol has a low tendency to bind to soil or sediment.

B. Partitioning

Isopropanol is miscible in water. Volatilisation from water surfaces or moist soil surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant of 0.821 Pa m^3/mole. It is also expected to volatilise from dry soil surfaces based upon its vapour pressure (Pub Chem).

C. Biodegradation

Aerobic biodegradation of isopropanol has been shown to occur rapidly under non-acclimated conditions, based on a result of 49% biodegradation from a 5-day BOD test (Bridie et al., 1979). Additional biodegradation data developed using standardised test methods show that isopropanol is readily biodegradable in both freshwater and saltwater media (72 to 78% biodegradation in 20 days) (Price et al., 1974).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

No experimental data are available for isopropanol. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} value from log K_{ow} is 3.478 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.53 L/kg.

E. Bioaccumulation

Bioconcentration of isopropanol in aquatic organisms is not expected to occur based on a measured log K_{ow} of 0.05 (ECHA). Based on this estimated value, the substance is expected to have very high mobility in soil. If released to water, based on this value and its water solubility, it is also not expected to adsorb to suspended solids and sediment.

Volatilisation from water surfaces is expected with half-lives for a model river and model lake of 86 hours and 29 days, respectively (PubChem).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of isopropanol is low by the oral, dermal and inhalation routes. At high exposure levels, isopropanol is irritating to the eyes, nose and throat and may cause transient central nervous system depression. It is not a skin sensitiser, but in some individuals, there may be an allergic contact dermatitis due to cross-sensitisation to other alcohols, such as ethanol. Repeated high exposures cause reversible narcotic effects, consistent with other short-chain alcohols. Isopropanol is not genotoxic. Lifetime inhalation studies in rodents showed no carcinogenic effects. The weight-of-evidence indicates that

isopropanol is not a reproductive toxicant. In a two-generation reproductive toxicity study, the male mating index was affected by isopropanol exposure; the significance of this effect is, however, unclear. Developmental toxicity can occur at maternally toxic doses; but it is not a teratogen. Isopropanol also does not affect neurobehavioral development.

B. Acute Toxicity

The acute oral LD_{50} of isopropanol has been reported as 4,700 mg/kg, 5,300 mg/kg, 5,500 mg/kg and 5,400 mg/kg in rats; 4,500 mg/kg in mice; and 5,030 mg/kg, 7,800 mg/kg and 7,900 mg/kg in rabbits (ECHA) [KI Score = 2].

The acute dermal LD_{50} in rabbits has been reported to be 12,900 mg/kg (ECHA) [KI Score = 2].

The acute inhalation 8-hour LC_{50} in rats was 19,000 ppm in females and 22,500 ppm in males (ECHA) [KI Score = 2]. Exposure of rats to 16,000 ppm for 8 hours resulted in four deaths out of six animals (ECHA) [KI Score = 2].

In an acute neurotoxicity study, male and female F344 rats were exposed to 0, 500, 1,500, 5,000 or 10,000 ppm isopropanol for 6 hours. A spectrum of behavioural effects indicative of narcosis, defined as a generalised loss of neuromotor and reflex function, was observed in animals of the 10,000 ppm group and to a lesser extent in the 5,000 ppm animals. Recovery from these effects was observed by 24 hours for the 10,000 ppm animals and by 6 hours for the 5,000 ppm animals. A concentration-dependent decrease in motor activity was observed for the 1,500 ppm males and the 5,000 ppm females. The results show that exposure of rats to isopropanol vapour produces transient, concentration-related narcosis and/or central nervous system sedation. The NOAEL for acute neurotoxicity is 500 ppm (ECHA) [KI Score = 2].

C. Irritation

Isopropanol applied to the intact or abraded skin of rabbits and guinea pigs produced negligible irritation. Liquid isopropanol is moderately irritating to the eyes of rabbits. Isopropanol produced little irritation when tested on the skin of six human subjects (ECHA) [KI Score = 1].

D. Sensitisation

There have been reports of isolated cases of dermal irritation and/or skin sensitisation. Except for three case reports, the positive reactions were observed on patch testing patients with contact dermatitis due to ethanol. These patients also had a positive reaction to ethanol.

E. Repeat Dose Toxicity

<u>Oral</u>

In a drinking water study, rats ingested 0.5 to 10% of isopropanol for 27 weeks and showed decreased body weight gain but no gross or microscopic tissue abnormalities (ECHA) [KI score = 3]. Increased formation of hyaline droplets in the proximal tubules was reported in male rats given 1–4% isopropanol in drinking water for 12 weeks (ECHA) [KI Score = 3].

A two-generation reproductive toxicity study has been conducted in rats given isopropanol by oral gavage. Pre-mating exposures were for at least 10 weeks for both generations. The results from this study are presented in the Reproductive Toxicity section (ECHA) [KI Score = 2].

Inhalation

F344 rats and CD-1 mice (both sexes) were exposed to 0, 100, 500, 1,500 or 5,000 ppm isopropanol for 6 hours/day, 5 days/week for 13 weeks. There were no deaths during the study. During and immediately following exposure to 5,000 ppm, ataxia, narcosis, hypoactivity and a lack of startle reflex were observed in some rats and mice. Narcosis was not observed in rats during exposure following week 2, suggesting some adaptation to isopropanol. During exposures to 1,500 ppm, narcosis, ataxia, and hypoactivity were observed in some mice, whereas only hypoactivity was observed in rats. Immediately following exposures, ataxia and/or hypoactivity were observed in a few rats or mice exposed to 5,000 ppm. Overall, the 1,500 and 5,000 ppm rats and the 5,000 ppm female mice showed increased body weights and/or body weight gain during the study. Liver weights relative to body weight were observed in rats of both sexes and the 5,000 ppm female mice; however, no corresponding microscopic changes were noted in the liver. Histopathological evaluation showed a slight increase in the size and frequency of hyaline droplets in the kidneys of the isopropanol-exposed rats. Excluding the clinical signs of CNS depression, the NOAEL for this study is 5,000 ppm (ECHA) [KI Score = 1].

In a subchronic neurotoxicity study, male and F344 rats were exposed by inhalation to 0, 100, 500, 1,500 or 5,000 ppm for 13 weeks. Neurobehavioural evaluations included a functional observation battery (FOB), motor activity and neuropathology. Effects of narcosis were observed in the 5,000 ppm groups only. There were no changes in FOB, but increased motor activity was noted in 5,000 female rats at weeks 9 and 13. Neuropathological examination revealed no exposure-related lesions in the nervous system. The NOAEL for acute effects is 500 ppm, and the NOAEL for subchronic neurotoxicity is 1,500 ppm (ECHA) [KI Score = 1].

An additional subchronic neurotoxicity study was conducted to clarify the increased motor activity findings. Female F344 rats were exposed to 0 or 5,000 ppm of isopropanol vapour for 6 hours/day, 5 days/week. Half of the animals in each group were exposed for 9 consecutive weeks and the other half for 13 consecutive weeks. After 9 weeks of exposure, the motor activity effect was reversible within 2 days after the last exposure. Subtle differences in the shape of the motor activity versus test session time curve were noted in both the 9-week and the 13-week exposed animals, although it was unclear whether these changes were treatment-related. Complete reversibility of these changes did not occur until 1 and 6 weeks after the last exposure in the 9 and 13 week exposure groups, respectively (ECHA) [KI Score = 2].

Male and female CD-1 mice were exposed by inhalation to 0, 500, 2,500 or 5,000 ppm isopropanol vapour 6 hours/day, 5 days/week for 18 months. An additional group of mice (all exposure levels) were assigned to a recovery group which were exposed to isopropanol for 12 months and then retained until study termination at 18 months. Survival was similar across all groups. Clinical signs were noted in the 5,000 ppm animals and included hypoactivity, lack of a startle reflex, ataxia, prostration and narcosis. Some of the animals in the 2,500 ppm group also showed hypoactivity, lack of a startle reflex and narcosis. Ataxia was the only exposure-related clinical sign that was noted for the 5,000 ppm animals

following exposure. There was a concentration-related increase in body weights and body weight gain in both the 2,500 and 5,000 ppm animals (both sexes). There were no exposure-related changes in the hematological parameters at the 12- and 18-month time points. At study termination, there was a concentration-related increase in liver weights in the females, with the 5,000 ppm females being statistically significant. Nonneoplastic lesions were limited to the testes (males) and the kidney. In the testes, enlargement of the seminal vesicles occurred in the absence of associated inflammatory or degenerative changes. The kidney effects included tubular proteinosis and/or tubular dilatation. The incidence of testicular and kidney effects was not increased in the isopropanol-exposed recovery animals. The NOAEL is 500 ppm (ECHA) [Kl Score = 2].

Male and female Fischer 344 rats were exposed to 0, 500, 2,500 or 5,000 ppm isopropanol vapour 6 hours/day, 5 days/week for 24 months. The mortality rates for all male rats were 82, 83, 91 and 100% for the 0, 500, 2,500 and 5,000 ppm groups, respectively. The corresponding values for the female rats were 54, 48, 55 and 69%. The main cause of death for the 5,000 ppm rats (both sexes), as well as for much of the mortality of the 2,500 ppm male rats, was chronic progressive nephropathy. Clinical signs were seen in the 5,000 ppm animals and included hypoactivity, lack of a startle reflex and narcosis. Some of the 2,500 ppm animals also showed a lack of a startle reflex. Body weight of the 5,000 ppm animals showed an initial decrease; from Weeks 6-72, body weights and body weight gain were increased. A similar pattern was seen in the 2,500 ppm males. Liver weights were increased in the ≥ 2,500 ppm male at 18 months, in the 2,500 ppm males at 24 months and in the 5,000 ppm females at 24 months. Kidney weights were increased in the 5,000 ppm males at 18 months and in the 5,000 ppm females at 24 months. Isopropanol exposure resulted in impaired kidney function, as indicated by various urine chemistry changes in male (2,500 and 5,000 ppm) and female (5,000 ppm) rats. Animals in these groups also exhibited histopathological effects in the kidneys which appeared to be an exacerbated form of chronic progressive nephropathy. The NOAEL is 500 ppm (ECHA) [Kl Score = 1].

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on isopropanol are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Isopropanol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* TA98, TA100, TA1535, TA1537)	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* TA97, TA98, TA100, TA102, TA104, TA1535, TA1537, TA1538)	-	-	2	ECHA
Sister Chromatid Exchange (V79 cells)	-	-	2	ECHA
Mammalian cell gene mutation (CHO/HGPRT)	-	-	1	ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Adenovirus (SA7) cell transformation (Syrian hamster embryo cells)	NA	-	2	ECHA

*+, positive; -, negative; NA, not applicable

In Vivo Studies

Male and female ICR mice were given a single intraperitoneal injection of 0, 350, 1,173 or 2,500 mg/kg isopropanol. There were no increases in micronuclei in the bone marrow polychromatic erythrocytes at the 24, 48 or 72-hour post-dosing time points at any dose level (ECHA) [Kl Score = 1].

G. Carcinogenicity

Oral

No studies are available.

Inhalation

The carcinogenic potential of isopropanol was evaluated via inhalation using three strains of mice. Male mice were exposed to 7.5 ppm of isopropanol for 3 to 7 hours/day, 5 days/week for 5 to 8 months. Animals were killed at either 8 or 12 months. There was no significant increase in the number of lung tumours observed (ECHA) [Kl Score = 3].

Male and female CD-1 mice were exposed by inhalation to 0, 500, 2,500 or 5,000 ppm isopropanol vapour for 6 hours/day, 5 days/week for 18 months. An additional group of mice (all exposure levels) were assigned to a recovery group which were exposed to isopropanol for 12 months and then retained until study termination at 18 months. There was no increased frequency of neoplastic lesions in any of the isopropanol-exposed animals (ECHA) [Kl Score = 1].

Male and female Fischer 344 rats were exposed to 0, 500, 2,500 or 5,000 ppm of isopropanol vapour for 6 hours/day, 5 days/week for 24 months. The mortality rates for all male rats were 82, 83, 91 and 100% for the 0, 500, 2,500 and 5,000 ppm groups, respectively. The corresponding values for the female rats were 54, 48, 55 and 69%, respectively. The main cause of death for the 5,000 ppm rats (both sexes), as well as for much of the mortality of the 2,500 ppm male rats, was chronic progressive nephropathy. The only neoplastic lesion noted was increased interstitial (Leydig) cell adenomas in male rats. The frequency of these tumours, although elevated above the control animals, was within the historical control range of the testing facility and within the range reported for control animals from the National Toxicology Program carcinogenicity studies (ECHA) [Kl Score = 1].

H. Reproductive Toxicity

In a two-generation reproductive toxicity study, Sprague–Dawley rats were dosed by oral gavage with 0, 100, 500 or 1,000 mg/kg isopropanol. There were seven parental deaths that were considered treatment-related: two high-dose F_0 females, two F_1 high-dose females,

one mid-dose F_0 female, and two low-dose F_1 males. Lactation body weight gain was increased in the 500 and 1,000 mg/kg females in both generations, and liver and kidney weights were increased in the 500 and 1,000 mg/kg groups in both sexes. Centrilobular hepatocyte hypertrophy was noted in some 1,000 mg/kg F_1 males. There were some kidney effects in the 500 and 1,000 mg/kg F_0 males and in all treated F_1 male rats. The kidney effects were characterised by an increased number of hyaline droplets in the convoluted proximal tubular cells, epithelial degeneration and hyperplasia, and proteinaceous casts. Increased mortality occurred in the high-dose F_1 offspring during the early postnatal period; no other clinical signs of toxicity were observed in the offspring from either generation. Offspring body weight, however, in the 1,000 mg/kg group was reduced during the early postnatal period. There was significant mortality in the F_1 weanlings (18/70) before the selection of the F_1 adults. A statistically significant reduction was observed in the F_1 male mating index of the 1,000 mg/kg group (73 versus 97% in the controls). There were no other treatment-related effects on reproduction, including fertility and gestational indices, or histopathology of the reproductive organs. A benchmark dose level of 420 mg/kg/day was calculated (lower bound on dose associated with a 5% response rate) for the decrease in the male mating index (ECHA) [KI Score = 1].

In a one-generation reproductive/embryotoxicity study, male and female Wistar rats were given 0, 0.5, 1.0 or 2.0% isopropanol in their drinking water. The calculated intakes for males were 383, 686 and 1,107 mg/kg/day (pre-mating) and 347, 625 and 1,030 mg/kg/day (18 weeks of treatment). The calculated intakes for females were 456, 835 and 1,206 mg/kg/day (premating); 668, 1,330 and 1,902 mg/kg/day (gestation); and 1,053, 1,948 and 2,768 mg/kg/day (postpartum). An immediate, statistically significant dose-dependent decrease occurred in water intake in the male rats. Intake was reduced ~5-14% (1% group; premating period) and ~30% (2% group; days 7-11 to end of study). Overall mean feed consumption was significantly lower in treated versus control animals. Male body weights (2% only) were reduced throughout the study. Water consumption was initially reduced in the 1% and 2% females, but the 2% group recovered to only ~70% of the control values (premating); it continued to be reduced during the gestation and lactation period. Mean maternal body weights were reduced (all treated groups) at the start of gestation, with partial recovery during the gestation period except for the 2% group. Overall weight gain during gestation in these groups were similar to the controls. Following parturition from PND 4 onward, the 2% dams had significantly lower body weights. There were no infertile males in any group, and no treatment-related effect on female fertility or on length of gestation. The number of pups/litter on GD 1 was reduced in the 2% group; because it was not replicated in the embryotoxicity portion, an increase in pup mortality during parturition or GD 0, followed by cannibalism of the dead pups by the dam was suggested. No macroscopic abnormalities were seen in females; nor was there any treatment-related histopathological changes seen in the reproductive tissue in the 2% parental animals. Absolute kidney weight and relative kidney, liver and spleen weights were increased in the 2% F_0 males; increased absolute liver and kidney weights and relative liver weights in the 2% F_0 females. In the embryotoxicity portion, there was a statistically significant increase in the total number of pre-implantation losses in the 2% animals. Whole body oedema was seen in 40% of the foetuses in 3/8 litters in the 2% group. No macroscopic abnormalities of the viscera of these foetuses were detected, and the incidence of oedema was not related to gender. In the one-generation portion, postnatal pup survival and in the average pup weight (by PND 7) were decreased in the 2% group. F_1 generation animals of both sexes showed increased relative liver weights at all dose levels, and the 2% males had higher relative kidney weights. A slight but significant decrease in absolute brain weight and increase in relative empty cecum weights in both sexes of the 2% F_1 generation group was observed. No treatment-related gross

abnormalities were observed in the F_1 generation animals at necropsy. The NOAEL for reproductive toxicity is 2% in drinking water, the highest dose tested (ECHA) [KI Score = 1]. The effects of isopropanol (2.5% in drinking water) on the reproduction and growth of rats were assessed in a multigenerational study. No reproductive toxicity was observed. The NOAEL for reproductive toxicity is 2.5% isopropanol in drinking water (ECHA) [KI Score = 4].

Isopropanol was administered as a 3% solution in drinking water to Wistar rats. Reduced parental body weight gain, food, and water consumption were observed in the treated animals compared with the controls. Fertility, litter size and pup weights at postnatal days 4 and 21 were reduced in treated animals compared with the controls. In the second generation, the isopropanol concentration was reduced to 2%, and there were essentially no effects (ECHA) [KI Score = 4].

I. Developmental Toxicity

Oral Studies

Isopropanol was given at concentrations of 0, 0.5, 1.25 or 2.5% in the drinking water to female Wistar rats on GD 6 to 16. The calculated intakes of isopropanol during GD 6-16 were 596, 1,242 and 1,605 mg/kg/day. There was an immediate reduction in water intake in the 2.5% dose group, and this was statistically significant throughout the treatment period when compared to controls. A smaller reduction in water intake was also seen in the 1.25% females (statistically significant during GD 6-9), with no change in the 0.5% females. Palatability of the drinking water may have been the problem since water intake significantly increased the first day following the end of the treatment period for all dose groups. Feed consumption patterns paralleled the water consumption during and after treatment in the mid- and high-dose groups. Overall, mean body weights of the 2.5% females were lower than the controls from GD 7 to termination. Effects on weight gain in the 0.5% and 1.25% females were limited to a failure to gain weight during the first (0.5%) and second (1.25%) day of treatment. There were no treatment-related effects in post-implantation loss, mean number of implantation sites or live foetuses. There was a slight dose-dependent decrease in mean litter weight and a significant decrease in mean foetal weight in the 1.25% and 2.5% groups. A statistically significant increase in variations was observed, indicative of a lower degree of ossification in the treated animals. There was a dose-dependent decrease in the number of foetuses with the 4th sacral arch and a dose-dependent increase in the number of foetuses with less than 2 caudal arches. The sternum also showed reduced ossification because there were increased numbers of foetuses with small, absent or incompletely ossified sternebrae. The NOAEL for maternal and developmental toxicity is 596 mg/kg/day (ECHA) [KI Score = 1].

In a rat developmental study, female Sprague–Dawley rats were dosed by oral gavage with either 0, 400, 800 or 1,200 mg/kg of isopropanol during gestational days 6 to 15. Two dams (8%) died at 1,200 mg/kg and one dam (4%) died at 800 mg/kg. At 1,200 mg/kg, maternal body weights were reduced throughout gestation (GS 0-20; 89.9% of control value), associated with reduced gravid uterine weight. There were no other treatment-related effects on the dams. Foetal body weights per litter were also significantly reduced at the 800 and 1,200 mg/kg dose levels, but there were no teratogenic effects. The NOAEL for maternal and developmental toxicity is 400 mg/kg/day, respectively (ECHA) [KI Score = 1]. In a rabbit developmental study, female New Zealand white rabbits were dosed by oral gavage with either 0, 120, 240 or 480 mg/kg of isopropanol during gestational days 6 to 18. At 480 mg/kg, isopropanol was unexpectedly toxic to pregnant female rabbits, resulting in the deaths of four does (26%). Maternal body weights were significantly reduced during

treatment (gestational days 6–18) and were associated with reduced maternal food consumption during this period. Profound clinical signs were noted at 480 mg/kg and included flushed and/or warm ears, cyanosis, lethargy and laboured respiration. No adverse maternal effects were noted at 120 or 240 mg/kg. There were no developmental or teratogenic effects at any dose tested. The NOAELs for maternal and developmental toxicity are 240 and 480 mg/kg/day, respectively (ECHA) [KI Score = 1].

Isopropanol was given by oral gavage to Sprague–Dawley rats from gestational days 6 to 21 in doses of 0, 200, 700 or 1,200 mg/kg. The dams were allowed to deliver, litters were culled on postnatal day (PND) 4, pups were weaned on PND 22, and their dams were killed. Weaned pups were assessed for day of testes descent or vaginal opening, motor activity, auditory startle and active avoidance. The pups were killed on PND 68. Some of the pups were taken from each dose group and were perfused in situ for pathological examination of the central nervous system. There were no biologically significant findings in the behavioural tests, no changes in organ weights and no pathological findings of note. Thus, there was no evidence of developmental neurotoxicity from isopropanol exposure (ECHA) [KI Score = 1].

Inhalation Studies

Pregnant female Sprague Dawley rats were exposed to 0, 3,500, 7,000 or 10,000 ppm isopropanol for 7 hours/day during gestational days 1–19. The animals showed unsteady gait and narcotisation during initial exposures in the mid- and high-dose groups; reduced food consumption and reduced weight gain were also noted in both the mid- and high-dose groups. Foetal body weights per litter were reduced in all dose groups. Exposure to 10,000 ppm also resulted in failure of implantation, fully resorbed litters, increased resorptions per litter and increased incidence of cervical ribs. The NOAEL for maternal toxicity is 3,500 ppm. The LOAEL for developmental toxicity is 3,500 ppm; a NOAEL was not established (ECHA) [KI Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for isopropanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-cancer

Oral

The repeated-dose toxicity studies on isopropanol by the oral route are inadequate for the purposes of risk assessment. There is, however, a well-conducted two-generation reproductive toxicity study, in which rats were dosed by oral gavage up to 1,000 mg/kg/day (Bevan et al., 1995). Allen et al. (1998) calculated a benchmark dose level of 420 mg/kg/day (lower bound on dose associated with a 5% response rate for the decrease in the male mating index). The Point of Departure (POD) of 420 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1
Oral RfD = 420/(10 x 10 x 1 x 10 x 1) = 420/1000 = 0.4 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (0.4 x 70 x 0.1)/2 = 1.4 mg/L

B. Cancer

Isopropanol was not carcinogenic to rats or mice in chronic inhalation studies. Therefore, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Isopropanol is a flammable liquid.

Isopropanol does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Isopropanol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on isopropanol.

Table 3: Acute Aquatic Toxicity Studies on Isopropanol

Test Species	Endpoint	Results	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	9,640 mg/L	2	ECHA
Daphnia magna	24-hour EC_{50}	> 10,000 mg/L	2	ECHA

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies on diethanolamine.

Table 4: Chronic Aquatic Toxicity Studies on Isopropanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Daphnia magna	16-day NOEC	141 mg/L	4	ECHA
Daphnia magna	21-day NOEC	30 mg/L	4	OECD, 1977a,b
Scenedesmus quadricauda	7-day NOEC	1,800 mg/L	2	ECHA

C. Terrestrial Toxicity

An EC_{50} value of 2,100 mg/L was determined from a lettuce seed germination test (Reynold, 1977) [Kl score = 2].

D. Calculation of PNEC

The PNEC calculations for isopropanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute $E(L)C_{50}$ values are available for fish (9,640 mg/L) and invertebrates (> 10,000 mg/L). Results from chronic studies are available for invertebrates (16- and 21-day NOECs for *Daphnia* are 141 and 30 mg/L, respectively). On the basis that the data consists of acute studies from two trophic levels and a chronic study from one trophic level, an assessment factor of 100 has been applied to the lowest reported NOEC of 30 mg/L for invertebrates. The $PNEC_{water}$ is 0.3 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.2 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.87/1280) \times 1000 \times 0.3$
$= 0.2$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water}$ = 0.8 + [0.2 x Kp_{sed})1000 x BD_{solid}]
= 0.8 + [0.2 x 0.14/1000 x 2400]
= 0.87 m^3/m^3

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
Kp_{sed} = K_{oc} x f_{oc}
= 3.478 x 0.04
= 0.14 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for isopropanol calculated from EPI Suite™ using Log K_{ow} is 3.478.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.014 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil}$ = (Kp_{soil}/BD_{soil}) x 1000 x $PNEC_{water}$
= (0.07/1500) x 1000 x 0.3
= 0.014 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
Kp_{soil} = K_{oc} x f_{oc}
= 3.478 x 0.02
= 0.07 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for isopropanol calculated from EPI Suite™ using K_{ow} is 3.478 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Isopropanol is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 0.05 and a calculated BCF of 1, isopropanol does not meet the screening criteria for bioaccumulation.

The chronic toxicity data on isopropanol show a NOEC of > 0.1 mg/L. The acute E(L)C_{50} values for isopropanol are > 1 mg/L. Thus, isopropanol does not meet the screening criteria for toxicity.

The overall conclusion is that isopropanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 2

Eye Irritant Category 2

STOT Single Exposure Category 3 [Narcosis]

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. If respiratory irritation, dizziness, nausea or unconsciousness occurs, seek immediate medical assistance. Give artificial respiration if victim is not breathing. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide. Do not use straight streams of water.

Specific Exposure Hazards

Highly flammable. Vapours are flammable and heavier than air. Vapours may travel across the ground and reach remote ignition sources causing a flashback fire danger. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. All equipment used when handling the material must be grounded. A vapour suppressing foam may be used to reduce vapours. Use clean non-

sparking tools to collect absorbed material. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Prevent exposure to ignition sources (i.e., use non-sparking tools and explosion-proof equipment). Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation. Use proper bonding and/or ground procedures. However, bonding and grounds may not eliminate the hazard from static accumulation. Peroxides may form upon prolonged storage. Exposure to light, heat or air significantly increases peroxide formation. If evaporated to a residue, the mixture of peroxides residue and material vapour may explode when exposed to heat or shock.

Storage

Keep container tightly closed. Store in a cool, well-ventilated area away from heat and light. Storage containers should be grounded and bonded. Fixed storage containers, transfer containers and associated equipment should be grounded and bonded to prevent accumulation of static charge. See SDS for suitable materials and coatings.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for isopropanol in Australia is 400 ppm as an 8-hour TWA and 500 ppm as a 15-min STEL.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN 1219 (Isopropanol)

Class 3

Packing Group II

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Allen, B; Gentry, R; Shipp, A; Van Landingham, C. (1998). Calculation of benchmark doses reproductive and developmental toxicity observed after exposure to isopropanol. Regul Toxicol Pharmacol 28: 38-44. http://dx.doi.org/10.1006/rtph.1998.1226

Bevan C., Tyler T.R., Gardiner T.H., Kapp Jr. R.W., Andrews L. and Beyer B.K. (1995). Two generation reproductive toxicity study with isopropanol in rats. J. Appl. Toxicol. 15(2):117-123.

Bridie, A.L., Wolff, C.J.M., and Winter, M. (1979). BOD and COD of some petrochemicals. Water Res. 13: 627-630.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (1997a). IUCLID Data Set for 2-Propanol (CAS No. 67-63-0), UNEP Publications.

OECD. (1997b). Screening Information Dataset (SIDS) Initial Assessment Report for 2-Propanol (CAS No. 67-63-0), UNEP Publications.

Price, K.S., Waggy, G.T., and Conway, R.A. (1974) Brine shrimp bioassay and seawater BOD of petrochemicals. J. Water Pollut. Contr. Fed., 46: 63-77.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

Reynold, T. (1977). An anomalous effect of isopropanol on lettuce germination. Plant Sci. Lett. 15: 25-28.

USEPA. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

MAGNESIUM SILICATE HYDRATE (TALC)

This dossier on magnesium silicate hydrate (talc) presents the most critical studies pertinent to the risk assessment of this substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dioxosilane; oxomagnesium; hydrate

CAS RN: 14807-96-6

Molecular formula: $H_2Mg_3O_{12}Si_4$

Molecular weight: 379.27 g/mol

Synonyms: Talcum, oxosilanediol, trimagnesium; dioxido(oxo)silane; hydroxy-oxido-oxosilane, dioxosilane; oxomagnesium; hydrate

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Magnesium Silicate Hydrate (Talc)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White solid odorless powder	2	ECHA
Melting Point	1,500°C @ 101.3 kPa	2	ECHA
Boiling Point	This substance is a solid that melts above 300°C	-	-
Density	2700 kg/m³ @ 20°C	2	ECHA
Vapour Pressure	0 Pa at 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-9.4 @ 25°C	2	ECHA
Water Solubility	0.0001 g/L @ 25°C; insoluble in water	2	ECHA
Flash Point	ND	-	-
Auto flammability	ND	-	-
Viscosity	Not applicable as substance is a solid.	2	ECHA
Dissociation constant	ND because the substance is insoluble in water	-	ECHA

ND – not determined

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Magnesium silicate hydrate (talc) is an inorganic substance for which biodegradation is irrelevant. Moreover, it will not bioaccumulate and has a low potential to adsorb to soil.

B. Biodegradation

As an inorganic substance, magnesium silicate hydrate (talc) will not biodegrade. Soil and sediment degradation studies are not considered to be applicable as the test material is essentially insoluble in water and consists of materials which occur naturally in these compartments (ECHA).

C. Environmental Distribution

Magnesium silicate hydrate (talc) is insoluble in water. The log K_{OC} of was estimated to be 1.5027 which is equal to a K_{OC} value of 31.82 L/kg using the KOCWIN v2.00 QSAR method (ECHA). Based on this K_{oc} value, if released to soil, magnesium silicate hydrate (talc) is expected to have a low potential for adsorption. If released into water, the substance has a low potential for adsorption to sediment or suspended solids.

D. Bioaccumulation

There is no potential for bioaccumulation. Due to its inherent chemical-physical properties, such as absence of lipophilicity as well as the capability of the organism to excrete absorbed SiO_2 components, bioaccumulation can be disregarded. Magnesium is widespread in living cells and does not bioconcentrate in aquatic organisms (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Talc is a mineral composed of hydrated magnesium silicate. Talc is essentially non-toxic by the oral and dermal routes. Talc is non-irritating to the eyes and skin. There was no toxicity or carcinogenic effects in rats. Talc is not genotoxic. No developmental toxicity was reported in pregnant female rats, mice or rabbits given oral doses of talc.

B. Basic Toxicokinetics

Inhalation

To determine the deposition, distribution and clearance of talc, 44 female Syrian golden hamsters received a single 2-hour nose-only exposure to a neutron-activated talc aerosol and sub-groups of 4 animals were then killed at 11 different intervals from 15 minutes to 132 days after exposure.

The talc tested was a commercial baby powder. Nine unexposed control animals were used; four were killed on the day the test animals were exposed and five were killed on the final day of the study. The aerosol exposure system had 7 tiers of exposure ports, and the talc aerosol was passed through a cyclone elutriator to remove particles that were larger than ~10 µm in diameter; the activity median aerodynamic diameter was 6.4-6.9 µm. The mean aerosol concentration was 40 and 75 µg/L at the 15 to 30 and 60 to 90-minute sampling periods, respectively. In the presentation of the results, the γ-ray counts from the controls were expressed as µg talc equivalent, and the γ-ray counts of the exposed animals were not corrected for control values.

Variations among animals killed at the same time were attributed to variations in aerosol concentration at different tiers. The mean pulmonary talc content in the lungs of test animals at various time intervals was 33.08 µg (15 minutes after exposure), 24.08 µg (100 minutes), 42.70 µg (4 hours), 18.75 µg (21 hours), 21.30 µg (2 days), 21.03 µg (after 4 days), 13.85 µg (after 8 days) and 8.95 µg (after 18 days); the mean for the Day 0 control animals was 1.78 µg. The biological half-life

of the talc deposited in the lungs was 7 to 10 days. At the time of termination of the final group, i.e., 132 days, there was no statistically significant difference in the talc burden of the lungs of test (3.70 µg) and control (2.30 µg) animals. The amount of talc in the liver, kidneys and lungs was also determined; the only statistically significant differences compared to controls in any of these organs were found in the liver. There was a decrease at 4 hours compared to day 0 controls, an increase at Day 36 compared to both Day 0 and Day 132 controls, and an increase on Day 68 compared to Day 132 controls.

Analysis of the data using the Kruskal-Wallis test showed that there were no significant differences among the mean talc burden values for the liver, kidneys and ovaries, including the control values, and that there was no significant trend, indicating there was no translocation of talc to these tissues.

As noted, no translocation from the respiratory tract to other tissues was found in this study, and the clearance of talc from the lungs was complete within 4 months after exposure.

Oral

In one study, six female Syrian golden hamsters (outbred Ela:ENG strain) were dosed by gavage with 1 mL neutron-activated talc suspended in physiological saline containing 0.6% (w/w) 1% methyl cellulose, and the animals were killed 24 hours after dosing. The talc used was a commercial baby powder.

Four hamsters were dosed similarly with a non-irradiated talc solution. The neutron-activated talc was exposed to an integrated neutron flux of 7 x 1,016 n/cm^2 30 days prior to dosing. The skinned carcass, gastrointestinal (GI) tract, lungs, liver, kidneys and excreta were analysed for isotopes 60 Co and 46 Sc by gamma-ray spectrometry, and the gamma-ray counts were compared with those of four hamsters that were not dosed with talc.

The γ-ray counts of the tissue and excreta of the dose animals were equivalent to a total of 2.94 mg talc. Based on γ-ray counts, 74.5% of the neutron-activated talc was recovered in the faeces and 23.5% was recovered in the GI tract, while 1.91% was recovered in the skinned carcass, 0.09% in the urine, 0.04% in the kidneys and 0.02% in the liver. The amount found in the urine of the hamsters given irradiated talc was statistically significantly increased compared to the controls. No talc was recovered in the lungs (ECHA) [KI score = 2].

In a second oral study, four LACA female mice were given a single oral dose of 40 mg/kg [3H] talc. Two mice were killed at 6 hours and two at 24 hours after dosing. In the mice killed 6 hours after dosing, 95 and 96% of the radioactivity was recovered in the large intestines and faeces, 9 and 7% was recovered in the small intestines and stomach, and 0.7 and 0% in the urine of each mouse. In the two mice killed 24 hours after dosing, 99 and 101% of the radioactivity was recovered in the large intestines and faeces, 4 and 6% was recovered in the small intestines and stomach, and 1.3 and 1.5% in the urine of each mouse. Less than 0.005% of the radioactivity was found in the carcass of any of the mice (ECHA) [KI score = 2].

In a third oral study, three male Wistar albino rats were given a single oral dose and three rats were given six daily oral doses by gavage of 50 mg/kg body wt [3H] talc. After the last dose, urine and faeces were collected every 24 hours for 4 days and on Day 10; the rats were then killed. Within 24 hours after administration of the single dose, approximately 75% of the radioactivity was recovered in the faeces and only 1% was recovered in the urine. After 96 hours, a total of 95.8% of the dose was excreted in the faeces and 1.7% in the urine, with a total excretion of 97.5% of the dose. No radioactivity was recovered in the liver or kidneys 10 days after a single dose of talc. On Day 10 in

the rats given six daily doses of [3H] talc, there was no radioactivity found in the faeces or livers, and there was a trace of radioactivity (< 0.02%) in the kidneys of these rats (ECHA) [Kl score = 2].

C. Acute Toxicity

Oral

A single oral dose of 5,000 mg/kg of talc prepared as an 18.3% (w/v) suspension in saline was administered to 10 male rats. All animals survived, and there were no signs of toxicity. In conclusion, the median lethal dose of Talc (Mg3H2(SiO3)4) after a single oral administration to male rats, observed over a period of 14 days is: LD50 > 5,000 mg/kg body weight (ECHA) [Kl Score = 2].

Inhalation

Groups of 5 male and female Wistar rats were treated with magnesium hydroxide as aerosol during 4 hours. No mortality or other relevant adverse effects were observed. An inhalatory LC_{50} (4-hour) value for magnesium hydroxide exceeding 2.1 mg/L was determined, being the maximum feasible concentration that could be tested (ECHA) [Kl Score = 2].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed. Five males and five female Wistar rats were dermally exposed to a single talc dose of 2,000 mg/kg.

Approximately 24 hours before the test, the fur was removed from the dorsal area of the trunk using an electric clipper. Care was taken to avoid abrading the skin, and only animals with healthy intact skin were used. No less than 10% of the body surface was cleared for the application.

The test item was applied at a single dose, uniformly over an area which was approximately 10% of the total body surface. The test item was held in contact with the skin throughout a 24-hour period. At the end of the exposure period the residual test item was not removed.

Under the conditions of this study, single dermal application of the test item magnesium chloride hexahydrate to rats at a dose of 2,000 mg/kg body weight was associated with no mortality. The dermal LD_{50} was determined to be > 2,000 mg magnesium chloride hexahydrate/kg body weight (ECHA) [Kl Score = 2].

Dermal

No studies were available.

D. Irritation

Skin

An *in vitro* skin irritation test was carried out with the reconstituted three-dimensional human skin model EPISKIN-SM™ (Skinethic). This skin model consists of normal (non-cancerous), adult human-derived epidermal keratinocytes (NHEK) which have been cultured to form a multilayered, highly differentiated model of the human epidermis. The NHEK are cultured on chemically modified, collagen-coated cell culture inserts. A highly differentiated and stratified epidermis model is

obtained after a 13-day culture period and is comprised of the main basal, supra basal, spinous and granular layers and a functional stratum corneum.

The test item showed no irritant effects. The mean relative tissue viability (% negative control) was ≥ 50% (112.9%) after 15-minute treatment and 42-hour post incubation. The controls confirmed the validity of the study. The mean OD550 of the three negative control tissues was ≥ 0.6. The mean relative tissue viability (% negative control) of the positive control was ≤ 30% (22.6%). The standard deviation of replicate tissues of all dose groups was ≤ 30% (1.4% - 9.4%). It can be concluded that talc is non-irritating to skin (ECHA) [KI Score = 2].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) study was performed using magnesium chloride hexahydrate as a surrogate substance for talc. A dose of 0.1 g of the test item was applied at a single dose in the conjunctival sac of one eye of each test animal after pulling the lower lid away from the eyeball. The lids were then gently held together for about 1 second in order to prevent loss of the material. The untreated contralateral eye served as control. Observations of the eye were made at 1, 24, 48 and 72 hours and 4 to 6 days.

Under the conditions of the study, single ocular instillation of the test item magnesium chloride hexahydrate to rabbits at a dose of 0.1 g produced irritant effects, which were fully reversible. Neither mortalities nor significant clinical signs of toxicity were observed. The test item is deemed to be non-irritating to eyes (ECHA) [KI Score = 2].

E. Sensitisation

No experimental data are available on the Talc ($Mg_3H_2(SiO_3)_4$) powder and silicates; however, there is long experience in humans. Data collected from industrial hygiene surveillance over the last 50 years do not indicate any potential for skin sensitisation. Despite the widespread cosmetic use of talc and special studies in volunteers (BIBRA, 1991) there are no indications of any allergenic effect (ECHA) [KI score = 3].

F. Repeated Dose Toxicity

Oral

A study equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies) was performed using male and female Wistar rats. Wistar rats (16 male and 16 female) were exposed to talc in feed which resulted in an amount taken up of 100 mg/kg/day. After feeding had been carried out for 101 days, the animals were observed until death and subsequently examined histopathologically.

One of the animals treated with talc showed a leiomyosarcoma of the stomach. Sarcomas, which were not associated with the talc treatment, were found in the uterus of two animals. No chronic pathological effect was associated with oral administration of talc over 5 months. No adverse effects were seen on general toxicity endpoints. Under the condition of this study, for a period of 101 days for male and female rats, the NOAEL of talc in a feeding study was 100 mg/kg/day (ECHA) [KI score = 2].

Inhalation

A study equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies) was performed using male and female Wistar rats. The Wistar rats (12 male and 12 female) were exposed whole body to aerosolised talc at a mean respirable dust concentration of 10.8 mg/m^3 for 7.5 hours per day, 5 days a week for 6 or 12 months.

Ten days after the end of each exposure period, 6 rats per group were killed; 12 rats per group died and 2 rats per group were unaccounted for. The remaining 4 rats per group were killed one year after the end of the exposure period. Minimal fibrosis was observed. Talc exposure led to distinct fibrosis that was comparable with that after exposure to chrysotile in the parallel group. A lung adenoma was detected in 1 of 24 animals treated with talc. In rats exposed by inhalation to 10.8 mg/m^3 Italian talc (grade 00000; ready milled; mean particle size, 25 µm) for 3 months, minimal fibrosis was observed, the degree of which did not change during the observation period after exposure. Animals that were exposed for 1 year had minimal to slight fibrosis, the degree of which had increased to moderate within 1 year after cessation of exposure.

A no observed adverse effect concentration (NOAEC) of 10.8 mg/m^3 was determined (ECHA) [KI Score = 2].

Dermal

No adequate studies for human health risk assessment are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on talc are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Talc

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (rat pleural mesothelial cells (RPMC)).	-*	ND	2	ECHA

*+, positive; -, negative
ND – not determined

Talc did not cause a statistically significant increase in sister chromatid exchanges (SCEs) and was not clastogenic. The test substance is non-mutagenic under the given experimental conditions (ECHA) [KI Score = 2].

In Vivo Studies

A study equivalent or similar to OECD Guideline 478 (Genetic Toxicology: Rodent Dominant Lethal Test) was performed per a rat dominant lethal assay on Sprague Dawley rats. Groups of 10 male rats were dosed by gavage with a single dose or once daily for 5 days with 30, 300, 3,000 or 5,000 mg/kg talc.

There were no dose-response or time trend patterns; talc did not induce dominant lethal mutations in this assay. Therefore, talc was not genotoxic in a rat dominant lethal assay (ECHA) [KI Score = 2].

H. Carcinogenicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed. In a feeding study of 16 male and 16 female Wistar rats, talc was added to the diet; this resulted in a dosage rate of 100 mg/kg/day. After feeding had been carried out for 101 days, the animals were observed until death (approximately 614 days) and subsequently examined histopathologically. One of the animals treated with talc showed a leiomyosarcoma of the stomach. Sarcomas, which were not associated with the talc treatment, were found in the uterus of two animals.

However, no differences in tumour incidence were noted between treated animals and 8 male and 8 female control animals fed basal diet throughout (average survival, 641 days).

Inhalation

In a lifetime experiment, three groups of 50 male and 50 female Syrian golden hamsters, 4 weeks of age, were exposed (whole body) by inhalation to an aerosol of talc baby powder that was prepared from Vermont talc by flotation (95% w/w platy talc with trace quantities of magnesite, dolomite, chlorite and rutile) for 3, 30 or 150 minutes per day, 5 days a week for 30 days. The mean aerosol concentration was 37.1 mg/m^3, with a measurable respiratory fraction of 9.8 mg/m^3 and a MMAD of 4.9 µm. A placebo exposed group comprised 25 males and 25 females. Two further groups of hamsters, 7 weeks of age, were exposed to talc aerosol for 30 or 150 minutes per day for 300 days. The mean aerosol concentration was 27.4 mg/m^3, with a measurable respiratory fraction of 8.1 mg/m^3 and a MMAD of 6.0 µm. Another placebo-exposed group comprised 25 males and 25 females. The survivors of the last two talc-exposed groups were killed at the age of 20 months.

No clinical signs of toxicity to talc were observed. The type, incidence and severity of lesions indicated no trend toward a dose-response and no statistically significant differences between exposed and control groups. The incidence of focal alveolar cell hyperplasia (25% in treated groups; 10% in controls) appeared to be affected by treatment, but a two-way weighted analysis showed no significant association. Thus, exposure of hamsters to talc via inhalation did not produce carcinogenic effects (ECHA) [KI Score = 2].

I. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed. Groups of 12-15 gravid Dutch-belted female rabbits were dosed orally with 9, 42, 195 or 900 mg/kg bw talc in corn oil on Days 6-18 of gestation. Eight gravid negative controls were given only vehicle and nine gravid positive controls were dosed with 2.5 mg/kg bw of 6-aminonicotinamide on Day 9 of gestation. The dams were killed on Day 29 of gestation. A total of 1/8, 4/15, 2/12, 5/15 and 2/13 dams of the negative control, 9, 42, 195 and 900 mg/kg bw dose groups, respectively, died or aborted before Day 29 of gestation, and the number of live litters for these groups was 6/7, 10/11, 8/10, 10/10 and 7/11, respectively. Details on Results (PO): Administration of up to 900 mg/kg bw talc on Days 6-18 of gestation had no discernible effect on nidation or on maternal survival.

The number of abnormalities did not differ between test and control animals.

Details on Results (F1): Administration of up to 900 mg/kg bw talc on days 6-18 of gestation had no discernible effect on nidation or on foetal survival. The number of abnormalities did not differ between test and control animals.

The NOAEL was considered to be 900 mg/kg bw/day for reproduction toxicity study. A NOAEL of > 900 mg/kg/day was determined for reproduction (ECHA) [KI Score = 2].

J. Developmental Toxicity

A GLP compliant study was performed. Groups of 20-22 gravid albino CD-1 mice and groups of 20-24 gravid Wistar rats were dosed by gavage with 0, 16, 74, 350 or 1,600 mg/kg bw talc as an anhydrous corn oil suspension on days 6-15 of gestation. The mice were killed on Day 17 and the rats on Day 20 of gestation and the number of implantation sites, resorptions sites, and live and dead foetuses, and the live pup body weights were recorded.

Maternal Toxicity: The administration of up to 1,600 mg/kg bw talc in corn oil had no effect on maternal endpoints.

Embryotoxic / Teratogenic Effects: The administration of up to 1,600 mg/kg bw talc in corn oil had no effect on developmental parameters and had no effect on foetal survival.

The NOAEL was considered to be 1,600 mg/kg bw/day for developmental toxicity (ECHA) [KI score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for talc follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

<u>Oral</u>

The NOAEL of 100 mg/kg/day from a chronic feeding study in rats was used to determine the oral RfD and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 100/(10 x 10 x 1 x 1 x 1) = 100/100 = 1 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

The carcinogenicity studies suggest talc is not a carcinogen. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Talc does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Talc is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Table 3 lists the results of the acute aquatic toxicity studies on magnesium silicate hydrate (talc).

Table 3: Acute Aquatic Toxicity Studies on Talc

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Fish (species unnamed)	96-hour LC_{50}	89,581 mg/L (QSAR)	2	ECHA
Daphnid	48-hour LC_{50}	36,812 mg/L (QSAR)	2	ECHA
Algae (species unnamed)	96-hour LC_{50}	7,203 mg/L	1	ECHA

Chronic Studies

No data are available. Short term aquatic toxicity tests reported in the literature on fish (LC_{50} *Brachydanio rerio* (Zebra fish) >100,000 mg/L/24 hr; for talc) show this substance is not toxic to aquatic life. On this basis the need for long term aquatic testing is waived (ECHA).

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

PNEC calculations for talc follow the methodology discussed in DEWHA (2009).

PNEC water

Acute experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (89,581 mg/L), *Daphnia* (36,812 mg/L), and algae (7,203 mg/L). By applying an assessment factor of 100 to the lowest E(L)C_{50} value of 7,202 mg/L from the acute studies, the $PNEC_{water}$ for talc is 72 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the low K_{ow} indicates that talc is not expected to partition to sediments. Therefore, a $PNEC_{sed}$ was not calculated.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Moreover, talc is biodegradable and due to its low K_{ow}, is not expected to partition to soil. Therefore, a $PNEC_{soil}$ was not calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Magnesium silicate hydrate (talc) is an inorganic substance and thus, biodegradation is not relevant. For the purposes of this PBT assessment, the persistent criteria are not considered applicable for this substance.

No data are available on bioaccumulation. However, based on the low log K_{ow}, and the inherent chemical-physical properties of magnesium silicate hydrate (talc), bioaccumulation is not expected. Thus, magnesium silicate hydrate (talc) does not meet the screening criteria for bioaccumulation.

Chronic aquatic toxicity data is not available. The E(L)C_{50} values from the acute aquatic toxicity studies on magnesium silicate hydrate (talc) are > 1 mg/L. Thus, magnesium silicate hydrate (talc) does not meet the criteria for toxicity.

Therefore, magnesium silicate hydrate (talc) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H332- Harmful if inhaled.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Rinse out mouth then drink plenty of water. Get medical attention.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Magnesium oxide, silicon oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Avoid dust formation. Avoid breathing vapours, mist of gas. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

No specific environmental precautions required.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light. Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has established an occupational exposure standard for exposure to talc of an 8 hour time weighed average (TWA) exposure limit of 2.5 mg/m^3 (containing no asbestos fibres).

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to

maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Talc is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council

BIBRA. (1991). The British Industrial Biological Research Association (BIBRA) Toxicity Profile – Talc. BIBRA, Carshalton, GB.

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

POLY(OXY-1,2-ETHANEDIYL), ALPHAHEXYL-OMEGA-HYDROXY-
(ETHYLENE GLYCOL-N-MONOHEXYL ETHER)

This dossier on poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy or ethylene glycol-n-monohexyl ether (EGMHE) does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of EGMHE in its use in in coal seam gas extraction activities. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on a well-defined surrogate ethylene glycol monobutyl ether (EGBE) (CAS RN 111-76-2), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-hexoxyethanol

CAS RN: 31726-34-8

Molecular formula: $C_8H_{18}O_2$

Molecular weight: 146.23 g/mol

Synonyms: Poly(oxy-1,2-ethanediyl), alpha-hexyl-omega-hydroxy-; ethylene glycol monohexyl ether; EGHE; alpha-Hexyl,omega-hydroxypoly(oxy-1,2-ethanediyl); hexyl alcohol, ethoxylated

SMILES: CCCCCCOCCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of EGBE (CAS No. 111-76-2)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	A colourless liquid. Odour is mild, ether-like, and slightly rancid.	2	ECHA
Melting Point	-74.8°C @ 101.3 kPa	2	ECHA
Boiling Point	171 – 171.5°C @ 101.3 kPa	2	ECHA
Density	900 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	80 Pa @ 20°C	2	ECHA
Partition Coefficient (log K_{ow})	0.81 (temperature not available)	1	ECHA
Water Solubility	900 g/L @ 20°C (fully soluble)	2	ECHA
Flash Point	67°C	2	ECHA
Auto flammability	230°C	2	ECHA
Viscosity	3.642 mm^2/s (3.28 mPa.s)	2	ECHA
Henry's Law Constant	0.041 Pa.m^3/mol	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

EGBE is readily biodegradable. It is not expected to bioaccumulate. EGBE has a low tendency to bind to soil or sediment.

B. Biodegradation

EGBE was considered readily biodegradable in an OECD 301B test. Degradation was 90.4% after 28 days; the 10-day window was met (ECHA) [KI score = 2]. Results from another OECD 301B test showed 63% and 74-75% degradation after 10 and 28 days, respectively (ECHA) [KI score = 2]. An OECD 301 D test showed 67-75% degradation after 15 days and 73-77% after 28 days (ECHA) [KI score = 2]. In a Zahn-Wellen (OECD 302B test), degradation of EGBE was 95% after 8 days, measured as DOC removal (ECHA) [KI score = 2].

C. Environmental Distribution

No experimental data are available for EGBE. Using KOCWIN in EPI Suite™ (U.S. EPA, 2017), the estimated K_{oc} value from log K_{ow} is 7.624 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 2.823 L/kg.

D. Bioaccumulation

No bioconcentration studies have been conducted on EGBE. EGBE is not expected to bioaccumulate based on the experimental log K_{ow} of 0.81 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

EGBE has low-to-moderate acute toxicity by the oral route. Species vary greatly in their susceptibility to acute toxicity by the dermal route, with the rabbit being the most sensitive species showing moderate toxicity, with the rat and guinea pig showing low toxicity (in descending order). EGBE is a skin and eye irritant; it is not a skin sensitiser. The major target organ effect of EGBE from exposure (regardless of the route of exposure) is the red blood cell (RBC). Animal studies show a hemolytic anemia (haemolysis of RBCs) from acute and chronic exposure to EGBE, resulting in effects in the kidney, liver and spleen. The hemolytic effect of EGBE is caused by the acid metabolite, 2-butoxyacetic acid (BAA). A number of species, including humans and guinea pigs, are relatively insensitive to the hemolytic effects of EGBE. Lifetime rodent studies by the inhalation route showed no carcinogenic effects in rats; however, liver tumours and hemangiosarcomas of the liver were seen in male mice, and forestomach tumours were seen in female mice. These tumours are thought to occur by a non-genotoxic mode-of-action and are only likely to occur in humans, if at all, at unrealistically high exposures (primarily because of kinetic/dynamic differences between mice and humans). Animal studies show that EGBE can cause reproductive and developmental toxicity, but only exposures that also cause parental or maternal toxicity.

B. Toxicokinetics/Metabolism

The toxicokinetics and metabolism of EGBE have been extensively studied and are reviewed in the EU Risk Assessment Report (EU, 2006) and in the U.S. EPA IRIS Toxicological Review of EGBE (U.S. EPA, 2010).

The major metabolite of EGBE is 2-butoxyacetic acid (BAA). EGBE is metabolised to butoxyaldehyde (BAL) by alcohol dehydrogenases, which is then further metabolised to BAA by aldehyde dehydrogenases. The metabolism of EGBE to BAA appears to be a saturable process. The other metabolites of EGBE are (in order of magnitude): the glucuronide conjugate of EGBE (a competing pathway to BAA formation and whose percentage increases relative to dose), the sulfate-conjugate of EGBE and ethylene glycol. Elimination is rapid and occurs mainly by urinary excretion. EGBE does not accumulate in tissues, and the metabolic profile does not change after repeated exposures compared to acute exposures.

Physiologically-based pharmacokinetic (PBPK) models has been developed for EGBE (Corley et al., 1994, 1997, 2005).

C. Acute Toxicity

The oral LD_{50} values for EGBE are presented in Table 2.

Table 2: Acute Oral LD_{50} Values for EGBE

Species	Results (mg/kg)	Klimisch Score	Reference
Rat	1,746 (fasted) 1,746 (fed)	1	ECHA
Rat	880 (male) 614 (female)	2	ECHA
Rat	1,480	2	ECHA
Rat	~1,900	2	ECHA
Rat	2,420	2	ECHA
Rat	2,100 (male) 1,850 (female)	2	ECHA
Mouse	1,519 (fasted) 2,005 (fed)	1	ECHA
Guinea pig	1,414	1	ECHA
Guinea pig	1,200	2	ECHA

The acute inhalation LC_{50} values for EGBE are presented in Table 3.

Table 3: Acute Inhalation LC_{50} Values for EGBE

Species	Exposure	Results (mg/L)	Klimisch Score	Reference
Rat	4-hour LC_0	2.4 (males) 2.2 (females)	1	ECHA
Rat	1- to 3-hour LC_0	> 29	2	ECHA

Species	Exposure	Results (mg/L)	Klimisch Score	Reference
Rat	3-hour LC_0 8-hour LC_{100}	1.44 4.25	2	ECHA
Rat	7-hour LC_{50}	> 4.26	2	ECHA
Rat	4-hour LC_{50} 8-hour LC_{50}	> 3.9 ~3.9	2	ECHA
Rabbit	7-hour LC_{50}	~400 ppm	2	ECHA
Guinea pig	1-hour LC_0	> 3.4 (males) > 3.1 (females)	2	ECHA
Guinea pig	7-hour LC_0	>400 ppm	2	ECHA

The dermal LD_{50} values for EGBE are presented in Table 4.

Table 4: Acute Dermal LD_{50} Values for EGBE

Species	Results (mg/kg)	Klimisch Score	Reference
Rabbit	> 2,000	1	ECHA
Rabbit	> 2,000	1	ECHA
Rabbit	612 (abraded)	2	ECHA
Rabbit	405	2	ECHA
Rabbit	567	2	ECHA
Rat	> 2,000	1	ECHA
Rat	2,275	2	ECHA
Guinea pig	> 2,000	1	ECHA
Guinea pig	0.23 mL/kg (intact) 0.30 mg/kg (abraded)	2	ECHA
Guinea pig	7.3 mL/kg	2	ECHA

D. Irritation

Application of 0.5 mL EGBE to the skin of rabbits for 4 hours under occlusive conditions was irritating. The mean of the 24, 48 and 72-hour erythema scores was 1.7. The mean of the 24, 48 and 72-hour oedema scores were 0.13. The erythema was not fully reversible within 14 days observation period (ECHA) [Kl score = 2]. Another study showed an irritating response to rabbit skin following a 24-hour exposure under occlusive conditions (ECHA) [Kl score = 2].

Instillation of 0.1 mL EGBE into the eyes of rabbits was irritating. The 24, 48 and 72-hour mean scores were: 0.89 for corneal opacity; 0.56 for iridial lesions; 2.6 for conjunctival redness; and 1.8 for chemosis. All effects were reversible within the 21-day observation period (ECHA) [Kl score = 1].

E. Sensitisation

EGBE was not considered to be a skin sensitiser in the guinea pig maximisation test (ECHA) [Kl score = 1].

F. Repeated Dose Toxicity

Oral

Male CR, COBS, CD-BR rats were dosed by oral gavage with 0, 222, 443 or 885 mg/kg EBGE, 5 days/week for 6 weeks. Bloody urine, which persisted through the third week of treatment, was observed in all of the ≥ 443 mg/kg animals; only one 222 mg/kg rat had bloody urine, which disappeared after the week 3 of exposure. Lethargy, unkempt hair coats, piloerection, rates, slight weakness and inactivity were also seen in these animals. Body weights and feed consumption were significantly reduced in the 885 mg/kg animals. Haematological effects were seen in the 885 mg/kg animals and included decreased haemoglobin, total red blood cells (RBCs), and increased MCH in all dose groups and showing a dose-related response. MCHC was decreased and MCV was increased in the ≥ 443 mg/kg animals. Alkaline phosphatase levels were elevated in the ≥ 443 mg/kg animals; and SGPT and glucose levels were increased in the 885 mg/kg group. Absolute and relative spleen and liver weights were increased in the ≥ 443 mg/kg animals. Relative liver weights were also increased in the 222 mg/kg animals. Enlarged, dark spleens were seen in the ≥ 443 mg/kg animals at gross necropsy. Histopathological examination showed stomach hyperkeratosis/acanthosis and splenic congestion in virtually all treated animals at all dose levels. Extramedullary haematopoiesis was observed in the spleens of treated animals. Liver effects were also seen in treated animals and included hepatocytomegally (885 mg/kg only), anisokaryosis (22 and 443 mg/kg), and hemosiderin deposition (≥ 443 mg/kg). Kidney effects were also seen in the treated animals and included hyaline droplet degeneration, proteinaceous casts and hemosiderin in the proximal tubules. The latter two effects were seen in the ≥ 443 mg/kg animals and were considered compound-related; the hyalaine droplets were seen in the controls and its significance is uncertain. The LOAEL for this study was considered 222 mg/kg/day based on adverse effects on the RBC and splenic congestion (it is difficult to discern what were primary effects, and what were secondary to the hemolytic effects); a NOAEL was not established (ECHA) [KI score = 2].

Male and female F344/N rats were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 13 weeks. Based on water consumption, the average daily intake was 0, 69, 129, 281, 367 or 452 mg/kg/day for males and 0, 82, 151, 304, 363 or 470 mg/kg/day for females. Supplemental groups were included for hematology and clinical chemistry observations at weeks 1 and 3. There was no mortality and no clinical signs of toxicity. Reduced body weight gain was seen in the ≥ 4,500 ppm animals, particularly in the females. Water consumption was also reduced in the higher dose groups, particularly for females. At each time point, there was a noticeable macrocytic and mildly hypochromic anemia. Reticulocyte counts were moderately increased in weeks 1 and 13; and erythrocyte counts were decreased at all time points in the ≥ 3,000 ppm males and the ≥ 1,500 ppm males. Thrombocytopenia was consistently observed at all time points in ≥ 4,500 ppm males and females; it also occurred in the 3,000 ppm females at week 13. Alkaline phosphatase was increased in the 6,000 ppm group on week 1 and in the ≥ 4,500 ppm groups on week 13. BUN and creatinine were increased, along with mild decreases in total protein and albumin, occurred at weeks 3 and 13; these changes were considered to be consistent with decreased feed intake. Absolute thymus weight were reduced in the ≥ 4,500 ppm groups. All other organ weight changes were considered secondary to body weight changes. Histopathological effects were seen in the liver, spleen and bone marrow of both male and female rats. The liver changes were primarily centrilobular hepatocellular degeneration and centrilobular Kupffer cell pigmentation. These changes were present in the majority of dosed rats, but they were more prevalent in the ≥ 3,000 ppm animals and were slightly more severe in

females. In addition, the cytoplasm of hepatocytes of treated rats was more eosinophilic and lacked the ampholytic-to-basophilic granularity typical of the controls. In the spleen, there was an increase in haematopoiesis and deposition of hemosiderin. In bone marrow there was an hyperplasia characterised by an increase of hematopoietic cells and decrease in marrow fat cells. All of these lesions were present in the majority of dosed rats, but they were more prominent in the ≥ 3,000 ppm animals. The LOAEL for this study is 750 ppm (69 and 82 mg/kg/day for males and females, respectively) based on the effects seen in the liver. A NOAEL was not obtained (NTP, 1993) [Kl score = 1].

Male and female B6C3F_1 mice were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 14 weeks. Based on water consumption, the average daily intake was estimated to be 0, 118, 223, 553, 676 or 694 mg/kg/day for males and 0, 185, 370, 676, 861 or 1,306 mg/kg/day for females. There was no mortality and no significant clinical signs of toxicity. Reduction in body weight gain was seen in the ≥ 3,000 ppm males and females. Water consumption did not appear to be affected by treatment. Organ weight changes were considered secondary to body weight gain reduction. No treatment-related gross or microscopic lesions in male or female mice were observed. The NOAEL for this study is 223 and 370 mg/kg/day for males and females, respectively. However, this study did not include hematology measurements (NTP, 1993) [Kl score = 1].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 5, 25 or 77 ppm (0, 24, 121 or 372 mg/m^3) EGBE 6 hours/day, 5 days/week for 90 days. Effects were more pronounced in females than males. In females, there was a slight hemolytic anemia, which was indicated by a minimal depression of RBC counts, haemoglobin and hematocrit; with a slight increase in MCH that was noted at week 2 and at the end of the exposure period. The haematological effects were non-progressive in that there was no increase in severity over time. Reduced body weight gain was seen at week 2, but not at the end of the study. No effects were seen in the males. The NOAECs for males and females were 77 ppm and 25 ppm, respectively (Dodd et al., 1983; ECHA).

Male and female F344/N rats were exposed by inhalation to 0, 31, 62.5, 125, 250 or 500 ppm EGBE 6 hours/day for 14 weeks. Six female rats were found moribund and killed during the study: five in the 500 ppm group and one in the 250 ppm group. Clinical signs were mainly in the ≥ 125 ppm animals and included abnormal breathing, pallor, red urine stains, nasal and eye discharge, lethargy and either increased salivation or lacrimation. All 500 ppm females developed alternating blue and white bands on their tails, particularly during the first two weeks of treatment, that caused them to self-mutilate and loose the distal portion of their tails. The mean final body weights and body weight gains were significantly reduced in the 500 ppm females. There was a persistent and exposure-related macrocytic, normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations, and erythrocyte counts in the ≥ 125 ppm males and ≥ 31 ppm females. The anemia was dose-related and statistically significant; at the lower doses, the effect was small (~5% in the 31 ppm females). Increases in reticulocyte and nucleated erythrocyte counts were seen in the ≥ 125 ppm males and the ≥ 62.5 ppm females, which are indicative of a erythropoietic response. Kidney weight increased in the 500 ppm males and the ≥ 125 ppm females. Liver weights were increased in the ≥ 250 ppm males and the ≥ 125 ppm females. Thymus weights were decreased in the 500 ppm females. There were histopathological changes in the surviving rats. Bone marrow necrosis and infarcts were found in the tails of all surviving 500 ppm females. Minimal hematopoietic cell proliferation of the spleen was seen

in the ≥ 62.5 ppm females and ≥ 250 ppm males. Bone marrow hyperplasia was increased in the ≥ 62.5 ppm females and ≥ 250 ppm males. Increased pigmentation of Kupffer cells in the liver was seen in the ≥ 62.5 ppm females and ≥ 125 ppm males. Renal tubule pigmentation was noted in most of the 250 ppm males, in all of the 500 ppm males, and all of the ≥ 125 ppm females. Minimal forestomach inflammation and hyperplasia were noted in a few of the ≥ 250 ppm males. Epithelial hyperplasia of the forestomach were noted in one female each in the ≥ 250 ppm groups. The NOAEC for males is 62.5 ppm based on haematological changes. The LOAEC for females is 31 ppm based on haematological changes; a NOAEC was not established (NTP, 2000) [Kl score = 1].

Male and female B6C3F_1 mice were exposed by inhalation to 0, 31, 62.5, 125, 250 or 500 ppm 6 hours/day for 14 weeks. There was mortality in the 500 ppm exposure group: two males and two females died; two males and two females were found moribund and were killed. Clinical findings were limited to the 500 ppm males and females that died or were killed. By study termination, body weight gains were significantly reduced in the ≥ 125 ppm males. There was a persistent and exposure-related normocytic (unlike rats), normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations, and erythrocyte counts in the ≥ 125 ppm males and ≥ 31 ppm females. The anemia was dose-related and statistically significant; at the lower doses, the effect on erythrocyte count and haemoglobin was small (1.8% and 2.2% in the 31 and 62.5 ppm females). The normocytic and normochromic erythrocytes were demonstrated by the lack of change in the mean cell volumes and mean cell haemoglobin concentrations, respectively. Relative, but not absolute, liver weighs were increased in the 250 ppm males. At 500 ppm, there were increased relative liver weights (both sexes), absolute liver weights (males), and relative kidney and heart weights (females). The livers of the 500 ppm males and ≥ 250 ppm females showed hemosiderin deposition in the Kupffer cells. Hemosiderin pigmentation was also seen in the kidney tubular cells of the 500 ppm animals (both sexes). Extramedullary hematopoietic cell proliferation (primarily erythroid) was seen in the ≥ 125 ppm males and ≥ 250 ppm females. In the forestomach, increased incidence of inflammation was seen in the ≥ 250 ppm females and epithelial hyperplasia in the ≥ 125 ppm females. The NOAEC for males is 62.5 ppm based on haematological changes. The LOAEC for females is 31 ppm based haematological changes; a NOAEC was not established (NTP, 2000) [Kl score = 1].

Male and female F344/N rats were exposed by inhalation to 0, 31, 62.5 or 125 ppm (0, 151, 302 or 604 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). For haematological and bone marrow analyses, additional groups of animals were exposed to 0, 62.5 or 125 ppm for evaluation at 3, 6 and 12 months; and to 31.2 ppm for 3 months (haematological examination only) and 6 months. Survival was similar across all groups, and there were no treatment-related clinical signs. Body weights of the 125 ppm females were generally lower than the controls from week 17 until study termination. There was a persistent and treatment-related macrocytic, normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations and erythrocyte counts at 3, 6 and 12 months in the 62.5 ppm females and the 125 ppm males. Some anemia also occurred at 3 and 6 months in the 31 ppm females and at 12 months in the 62.5 ppm males. In females, the anemia was characterised by a dose-related and significant fall in haematocrit, hemoglobin and erythrocyte count and an increase in MCV. The changes at 31 ppm were small (< 5%). Circulating reticulocyte and nucleated erythrocyte counts are indicative of an erythropoietic response to the anemia. There was about 15-35% decrease in the myeloid/erythroid ratio in the bone marrow of the 125 ppm rats (both sexes), particularly in the females. Significant changes in the ratio were also seen in the 125 ppm males and the 62.5 ppm females, but at only one time point. The severity of the response

was dose-related. Non-neoplastic changes occurred in the nose, liver and spleen. The incidence of hyaline degeneration of the olfactory epithelium were significantly increased in the ≥ 31 ppm males and in the ≥ 62.5 ppm females. The severity was minimal and did not change with increasing exposure concentration. The incidence of Kupffer cell pigmentation of the liver increased significantly in all exposed male and in the ≥ 31 ppm males and in the ≥ 62.5 ppm females; the severity increased in the 135 ppm of both sexes. The incidences of fibrosis in the spleen were significantly increased in the ≥ 62.5 ppm males, but not in females. The LOAEC for males is 31 ppm based on hematology and Kupffer cell pigmentation in the liver. The LOAEC for females is 31 ppm based on Kupffer cell pigmentation in the liver. A NOAEC for either sex was not established (NTP, 2000) [KI score = 2].

Male and female B6C3F_1 mice were exposed by inhalation to 0, 62.5, 125 or 250 ppm (0, 302, 604 or 1,208 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). For haematological and bone marrow analyses, additional groups of animals were exposed to 0, 62.5, 125 or 250 ppm for evaluation at 3, 6 and 12 months. Survival of the ≥ 125 ppm males were significantly less than the controls. Body weights of exposed males were generally less than the controls during the last 25 weeks of the study. The 250 ppm females had body weights that were generally lower (20%) than controls from week 30 to the end of the study. The 62.5 and 125 ppm females had lower body weights from about week 60 until the end of the study. There was a persistent and exposure-related normocytic and normochromic, responsive anemia, characterised by haematocrit, hemoglobin concentrations and erythrocyte counts. In general, the anemia lacked changes in mean cell volumes and mean cell haemoglobin concentrations. There were no treatment-related clinical signs. The changes occurred at the 3-, 6- and 12-month time points in the ≥ 125 ppm males and females. Some anemia also occurred at 6 months in the 62.5 ppm females, and there was some indication of a macrocytosis (as seen by a minimal increase in cell volume) in the 250 ppm females at 12 months. Circulating reticulocyte counts were increased in the ≥ 125 ppm males and females at 3 and 6 months and the 250 ppm females at 12 months; these changes are indicative of an erythropoietic response to the anemia. The bone marrow had no change in either cell counts or myeloid/erythroid ratio. A thromobocytosis (increased platelet counts) developed in the ≥ 62.5 ppm animals at 12 months , in the 250 ppm males at 6 months, the 250 ppm females at 3 and 6 months, and in the 125 ppm females at 6 months. At 62.5 ppm, the females showed reduced haemoglobin, hematocrit, erythrocyte count and increased platelets. The 62.5 ppm males showed an increased platelet count. All these changes were statistically significant with a clear dose-response, but the magnitude was small (< 5%), except for the platelet count (15-20%). Splenic hematopoietic cell proliferation was increased in the ≥ 125 ppm males and 250 ppm females, but it was not accompanied by any change in myeloid/erythroid cell ratio. Increased incidence of hemosiderin pigmentation occurred in the ≥ 62.5 ppm males and ≥ 125 ppm females, and increased bone marrow hyperplasia occurred in the ≥ 125 ppm males. The incidence of hyaline degeneration of the nasal olfactory epithelium and respiratory epithelium was increased in the ≥ 62.5 ppm females (but not in males). The severity of the lesion was minimal and did not change with increasing exposure concentration. There was no clear dose-response. There were forestomach lesions which consisted of ulcers (particularly in females), epithelial hyperplasia that was usually focal, and, particularly in females, frequently associated with ulceration. There was also a number of inflammatory changes in the urogenital system in the male mice only; these changes were not considered to be primarily related to treatment. The LOAEC for this study is 62.5 ppm based on haematological changes and increased platelet counts (at 12 months); a NOAEC was not established (NTP, 2000) [KI score = 1].

Dermal

Male and female New Zealand rabbits were given dermal application of 0, 10, 50 or 150 mg/kg EGBE 6 hours/day for 13 weeks. The highest dose was the maximum that could be tolerated without irritation from prolonged exposure. There were no clinical, haematological effects, clinical chemistry or histopathological changes that were considered treatment-related. The NOAEL for this study is 150 mg/kg/day (ECHA) [KI score = 1].

G. Genotoxicity

In Vitro Studies

Table 5 presents the results of the *in vitro* genotoxicity studies on EGBE.

Table 5: *In Vitro* Genotoxicity Studies on EGBE

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	NTP, 1993; NTP, 2000
Mammalian cell gene mutation (CHO cells/HGPRT)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	1	NTP, 1993; NTP, 2000

*+, positive; -, negative

In Vivo Studies

Male F344 rats were given a single daily intraperitoneal injection of 0, 7.03. 14.06, 28.12, 56.25, 112.5, 225 or 450 mg/kg EGBE for three consecutive days. Two of the five animals in the 450 mg/kg group died. There was no increase in micronuclei in the bone marrow polychromatic erythrocytes at any dose level (NTP, 2000) [KI score = 1].

Male B6C3F_1 mice were given a single daily intraperitoneal injection of 0, 17.19, 34.38, 68.78, 137.5, 275, 550 or 1,100 mg/kg EGBE for three consecutive days. All the animals in the 1,100 mg/kg group died. There was a statistically significant increase in the number of micronucleated polychromatic erythrocytes in the 137.5 mg/kg dose group only in a pairwise comparison with the controls. The analysis for trend was not significant and it was concluded that the test was negative (NTP, 2000) [KI score = 1].

H. Carcinogenicity

Oral Studies

No studies are available.

Inhalation Studies

Rats: Male and female F344/N rats were exposed by inhalation to 0, 31.2, 62.5 or 125 ppm (0, 151, 302 or 604 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks. Survival was similar across all groups. The incidence of benign or malignant

pheochromocytoma (combined) of the adrenal medulla in females exposed to 125 ppm EGBE was not significantly increased compared to the chamber controls, but it did exceed the historical control range. There was only one malignant pheochromocytoma, which occurred in the 125 ppm group. NTP concluded that there was no evidence for carcinogenicity in male rats and equivocal evidence for carcinogenicity in female rats (NTP, 2000) [KI score = 1].

Mice: Male and female $B6C3F_1$ mice were exposed by inhalation to 0, 62.5, 125 or 250 ppm (0, 302, 604 or 1,208 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). Survival of the ≥ 125 ppm male mice was significantly less than that of the controls. Increased incidence of tumours was seen in the forestomach of females and liver hemangiosarcomas in males.

Forestomach: There was a positive trend in the incidences of forestomach squamous cell papilloma and squamous cell papilloma or carcinoma combined in female mice. The incidences were significantly increased in the 250 ppm group, in which the only squamous cell carcinoma occurred. These incidences exceeded the historical control range for female mice. There was no significant increase in the incidence of these neoplasms in male mice, but they did exceed the historical control range for male mice. There was one squamous cell carcinoma, but it was in the 125 ppm group.

Liver hemangiosarcomas: There was a positive trend in the incidence of hemangiosarcomas in male mice, which was statistically significant in the 250 ppm group. The incidence at 250 ppm also exceeded the historical control range for this tumour in male mice. There was also a positive trend in the incidence of hepatocellular carcinomas, which was statistically significant in the 250 ppm group. There was, however, no change in the incidence of hepatocellular adenomas and carcinomas combined, because of a reduced incidence of hepatocellular adenomas in the treated groups. The tumour incidence in female mice were not significantly different from the controls.

The NOAEC for tumourigenicity in mice is 125 ppm, based on an increased incidence of liver hemangiosarcomas in males and squamous cell papillomas or carcinomas in females at 250 ppm (NTP, 2000).

I. Mode of Action (MOA) for Mouse Tumours from EGBE Exposure

Liver Hemangiosarcomas

The hypothesised key steps of the MOA are metabolism of EGBE to BAA, hemolysis of RBCs with release of haemoglobin and hepatic hemosiderin accumulation, followed by oxidative stress, modulation of gene expression, cell proliferation, promotion, and neoplasm, leading to the formation of liver tumours (U.S. EPA, 2010). These tumours are unlikely to occur in humans because exposures would have to be much higher than those for rats. *In vitro* data suggest there is a 40- to 150-fold difference in the dose that produces hemolytic changes in the RBCs of humans as compared to rodents. This difference is supported by the Carpenter et al. (1956) study in which no changes in erythrocyte fragility were measured in humans at the highest tested concentration, 195 ppm, but increased erythrocyte fragility was measured in co-exposed rats. In addition, simulations from a PBPK model (Corley et al., 2005) predict that, given the vapour pressure of EGBE, the maximum blood level of BAA that can be obtained from inhalation exposure would be lower than the predicted concentrations from

bolus exposures that have not resulted in hemolytic effects, and lower than concentrations that have been shown to produce an effect on human RBCs *in vitro* (Udden, 2002).

Forestomach Tumours

The incidence of squamous cell papilloma and carcinoma of the forestomach was increased in female mice exposed to 250 ppm EGBE (NTP, 2000). There was also an increase in squamous cell papillomas in male mice, but the incidence was not statistically significant. Forestomach papillomas and carcinomas were not seen in either male or female rats in the 2-year NTP studies. In addition to the tumours, there was also a statistically significant, dose-dependent increase in hyperplasia in mice (both sexes), and for ulceration in female mice. The incidence of ulceration was significantly increased in the 125 ppm male mice.

The hypothesised steps are metabolism to BAA, followed by tissue irritation and subsequent cytotoxicity, compensatory proliferation and the induction of forestomach tumours. Forestomach tumours are unlikely to occur in humans because of the anatomical differences between the human stomach and the mouse forestomach; and because EGBE exposures would have to be higher, if at all possible, in humans than in mice because of the differences between mice and humans in the production and clearance of BAA.

J. Reproductive Toxicity

Male and female Swiss CD-1 mice were given in their drinking water 0 0.5, 1.0 or 2.0% EGBE (equivalent to daily intakes of 0, 720, 1,340 and 2,050 mg/kg/day) during a continuous breeding protocol with a 7-day pre-mating period and a 98-day cohabitation period. There were significant adverse reproductive effects in the females at very high dose levels (≥ 1,340 mg/kg) which also caused severe toxicity, including death. Marginal reductions (3%) in pup weight were noted at 720 mg/kg in the first generation, but not in the second generation. The NOAELs for reproductive and developmental toxicity are 720 mg/kg/day. A NOAEL or LOAEL was not determined for systemic parental toxicity because this protocol is not designed to assess systemic toxicity. However, it was noted that reduced water consumption occurred at all dose levels (Morrissey et al., 1988, 1989; Heindel et al., 1990) [KI score = 1].

Male and female F344/N rats were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 13 weeks. Based on water consumption, the average daily intake was 0, 69, 129, 281, 367 or 452 mg/kg/day for males; and 0, 82, 151, 304, 363 or 470 mg/kg/day for females. Testis weights were unaffected by treatment, but the size of the uterus in the ≥ 4,500 ppm groups were reduced. Changes in uterine weight were considered by the authors to be secondary to the reduction in body weight gain rather than a direct effect of EGBE. Sperm concentration was slightly decreased in all treated males (not dose-related); all other sperm measurements were similar to controls. Oestrous cycle length was unaffected by treatment, although the ≥ 4500 ppm females spent more time in diestrous than the other groups. This correlated with the smaller uterine size, which was attributed to a secondary consequence of reduced body weight gain (NTP, 1993; ECHA) [KI score = 1].

K. Developmental Toxicity

Oral Studies

Pregnant female F344 rats were dosed by oral gavage with 0, 30, 100 or 200 mg/kg EGBE on GD 9-11; some animals sacrificed on GD 12 and others sacrificed on GD 20. Another group of pregnant female F344 rats were dosed by oral gavage with 0, 30, 100 or 300 mg/kg EGBE on

GD 11-13; some animals sacrificed on GD 14 and the others sacrificed on GD 20. At ≥ 100 mg/kg on GD 9-11 and GD 11-13, there was marked body weight reduction and/or weight gain, increased kidney and spleen weights, and severe hematotoxicity, in particular marked reduction in circulating red blood cells, haematocrit and hemoglobin, which occurred 24 hours post-treatment. By GD 20, the hematoxic effects were nearly reversed. These changes in organ weights and haematological parameters are indicative of hemolytic anemia and the compensatory haematological changes following cessation of exposure. Increased resorptions, non-live implants and adversely affected implants per litter in the 200 mg/kg treated dams (GD 9 – 11), and decreased foetal platelet count, but no embryolethality, in the 300 mg/kg treated dams (GD 11-13). There were no adverse effects seen on the cardiac system. Increased foetal lethality, but no increase in malformations, occurred in the 200 mg/kg dose (GD 9-11). Increased platelet count was also seen in the foetuses of the 300 mg/kg dose group (GD 11-13). The maternal NOAEL for this study is 30 mg/kg/day. The developmental NOAELs are 100 and 300 mg/kg/day when EGBE was given on GD 9–11 and GD 11-13, respectively (Sleet et al., 1991; ECHA) [Kl score = 1].

In a teratology probe study using the Chernoff-Kavlock assay, pregnant female CD-mice were dosed by oral gavage with 0, 350, 650, 1,000, 1,500 or 2,000 mg/kg EGBE during GD 8 to 14. Maternal toxicity was evident in the dams at dosed of ≥ 650 mg/kg. There were hemolytic effects (≥ 650 mg/kg) and mortality (≥ 1,500 mg/kg). At 1,000 and 1,500 mg/kg, increased resorption rates and numerically reduced number of viable foetuses were observed at 1,000 and 1,500 mg/kg. Cleft palates were seen in 4/43 foetuses (in one litter) at 1,000 mg/kg/day and 1/25 at 1,500 mg/kg. The NOAELs for maternal and developmental toxicity are 350 and 650 mg/kg/day, respectively (Wier et al., 1987; ECHA) [Kl score = 2].

In another Chernoff-Kavlock assay, CD-1 mice were dosed by oral gavage with 1,180 mg/kg/day EGBE (in corn oil) from GD 7 to 14, then allowed to litter and to rear pups to PND 3. Nineteen of the dams died (20%), maternal weight gain was reduced and there were only 24 viable litters (77%) from the surviving dams compared with 97% in the controls. There was no external malformations, pup survival to PND was unaffected and there was no other evidence of developmental toxicity (Schuler et al., 1984; ECHA) [Kl score = 2].

Inhalation Studies

Pregnant female F344 rats were dosed by oral gavage with 0, 25, 50, 100 or 200 mg/kg EGBE on GD 6-15. A dose-related increase in maternal toxicity was observed during the exposure period. There was hematuria (≥ 100 ppm); pale, cold extremities with necrosis of the tail tip (200 ppm); weight loss (≥ 100 ppm), reduction in food consumption (≥ 100 ppm) and water consumption (200 ppm). Absolute and relative organ weight reductions were also noted. Evidence of hemolytic anemia was found in the ≥ 100 ppm dams when blood samples were taken on GD 21. At 200 ppm, there was embryotoxicity (increased resorptions and decreased viable implants per litter) and fetotoxicity (retardations in skeletal ossification). There was no evidence of teratogenicity. The NOAECs for maternal and developmental toxicity are 50 and 100 ppm, respectively (Tyl et al., 1984; ECHA) [Kl score = 2].

Pregnant female New Zealand White rabbits were exposed by inhalation to 0, 25, 50, 100 or 200 ppm EGBE 6 hours/day during GD 6-18. At 200 ppm, four does died or were sacrificed by the third day after the onset of dosing, and four does aborted. All were pregnant. Pregnancy rates were similar across all groups. Body weight loss occurred in all groups including controls during exposure, but the highest difference was in the 200 ppm exposure group; by GD 15, body weights were significantly lower in the 200 ppm group. The high-dose group

had a significant reduction in maternal body weight (8%), gravid uterine weight (22%), and the number of total implants and viable implants. No other developmental effects (including teratogenicity) were noted. The NOAELs for maternal and developmental toxicity are 50 and 100 ppm, respectively (Tyl et al., 1984; ECHA) [Kl score = 2].

Pregnant female SD rats were exposed by inhalation to 0, 150 or 200 ppm EGBE 7 hours/day during GD 7-15. The only maternal effect noted was hematuria in the ≥ 150 ppm dams. There was no developmental toxicity. The NOAEC for developmental toxicity is 200 ppm. A conservative LOAEC for maternal toxicity is 150 ppm, with a NOAEC not established (Nelson et al., 1984) [Kl score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for EGBE follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

An oral RfD was derived by U.S. EPA (2010) based on the findings of the NTP chronic inhalation studies, the rationale being the limited oral database and because the critical endpoint, hemosiderin pigmentation, was more pronounced in the chronic inhalation study (NTP, 2000) versus the available subchronic oral study (NTP, 1993).

U.S. EPA used a route-to-route extrapolation from the NTP (2000) study for the derivation for the RfD. The dose metric used for animal-to-human and route-to-route (inhalation-to-oral) extrapolation for the derivation of the RfD is the area under the curve (AUC) of BAA at 12 months in arterial blood. This dose metric was used for dose-response modelling of chronic inhalation data to derive the point of departure (POD) of 133 µmol-hour/L, expressed as a BMDL based on animal data. The corresponding human BMDL was then back-calculated using the human PBPK model (Corley et al., 1994; Corley et al., 1997) to obtain an equivalent human oral drinking water dose ($BMDL_{HED}$) of 1.4 mg/kg/day. A simplifying assumption was used that the entire dose of drinking water EGBE was consumed over a 12-hour period each day.

Oral Reference Dose (oral RfD)

Oral RfD = $BMDL_{HED}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 1
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 1.4/(1 x 10 x 1 x 1 x 1) = 1.4/10 = 0.14 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (0.14 x 70 x 0.1)/2 = 0.5 mg/L

B. Cancer

Male mice developed hepatocellular carcinomas and hemangiosarcomas that appear to be exposure-related. The incidence of hemangiosarcomas was statistically significant and increased over both concurrent and historical control groups. The hepatocellular carcinomas were within the range of historical controls for male mice but are considered because the dose-response trend is significant and because a similar MOA has been suggested for this tumour. The incidences in the high dose group of these two tumour types were only slightly higher than the upper end of the range for historical controls. These two tumour types were not seen in mice.

The incidence of squamous cell papilloma and carcinoma of the forestomach was increased in female mice exposed to 250 ppm EGBE (NTP, 2000). There was also an increase in squamous cell papillomas in male mice, but the incidence was not statistically significant. Forestomach papillomas and carcinomas were not seen in either male or female rats in the 2-year NTP studies. In addition to the tumours, there was also a statistically significant, dose-dependent increase in hyperplasia in mice (both sexes), and for ulceration in female mice. The incidence of ulceration was significantly increased in the 125 ppm male mice.

The MOAs for these tumours reflect the non-genotoxic nature of EGBE and its metabolites. Both of these MOAs suggests that the MOAs have only limited quantitative significance to humans, principally due to kinetic/dynamic differences from the rodents (U.S. EPA, 2010; ECHA). Because of the MOA, a non-linear approach is used for the dose-response assessment, using the RfD that was derived for the non-cancer assessment. Doses of EGBE below the RfD would not be expected to produce hemolytic effects (i.e., hemosiderin deposition) and therefore is not expected to produce any increase in cancer risk.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

EGBE does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

EGBE is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 6 lists the results of acute aquatic toxicity studies conducted on EGBE.

Table 6: Acute Aquatic Toxicity Studies on EGBE

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hour LC_{50}	1,464	2	ECHA
Pimephales promelas	96-hour LC_{50}	2,137	2	ECHA
Pimephales promelas	96-hour LC_{50}	1,700	2	ECHA
Pimephales promelas	96-hour LC_{50}	1,580	2	ECHA
Lepomis machrochirus	96-hour LC_{50}	1,490	2	ECHA
Daphnia magna	48-hour EC_{50}	1,800	2	ECHA
Daphnia magna	48-hour EC_{50}	1,815	2	ECHA
Daphnia magna	48-hour EC_{50}	881 (cited) 1,100 (recalculated)	2	ECHA
Daphnia magna	48-hour EC_{50}	2,650	2	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50} NOEC	911 (biomass) 88	1	ECHA
Selenastrum capricornutum	72-hour EC_{50} NOEC	720 (biomass) 280	2	ECHA

Chronic Studies

A 21-day fish (*Brachydanio rerio*) study was conducted to examine the potential for endocrine disrupting effects; the study design was based on the OECD TG 204. The NOEC was > 100 mg/L (ECHA) [Kl score = 2].

The NOEC from a 21-day *Daphnia* reproduction study was 100 mg/L (ECHA) [Kl score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for EGBE follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (1,000 mg/L), *Daphnia* (1,100 mg/L) and algae (911 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 88 mg/L for algae. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 88 mg/L for algae. The $PNEC_{water}$ is 8.8 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.5 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.94/1280) \times 1000 \times 8.8$
$= 6.46$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.30/1000 \times 2400]$
$= 0.94\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= 7.624 \times 0.04$
$= 0.30$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for EGBE calculated from EPI Suite™ is 7.624 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.9 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.15/1500) \times 1000 \times 8.8$
$= 0.88$ mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
= 7.624 x 0.02
= 0.15 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for EGBE calculated from EPI Suite™ is 7.624 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Based on information for read-across substance EGBE, EGMHE is readily biodegradable; thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 0.81 for read-across substance EGBE, EGMHE does not meet the screening criteria for bioaccumulation.

The chronic toxicity data on read-across substance EGBE show NOECs of > 0.1 mg/L. Thus, EGMHE does not meet the screening criteria for toxicity.

The overall conclusion is that EGMHE is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]

Acute Toxicity Category 4 [Dermal]

Acute Toxicity Category 4 [Inhalation]

Skin Irritant Category 2

Eye Irritant Category 1

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

Due to structural analogy and clinical data, this material may have a mechanism of intoxication similar to ethylene glycol.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam (alcohol-resistant is preferred), dry chemical or carbon dioxide.

Specific Exposure Hazards

Container may rupture from gas generation in a fire. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light. Store in the following materials: carbon steel, stainless steel, phenolic lined steel drums. Do not store in: aluminium, copper, galvanised iron, galvanised steel.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace exposure standards have not been established for EGMHE in Australia. The workplace exposure standard for EGBE in Australia is 20 ppm (96.9 mg/m^3) as an 8-hour TWA and a 15-min STEL of 50 ppm (242 mg/m^3) with a skin [absorption] notation.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

EGMHE is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Carpenter, C.P., Pozzani, U.C., Weil, C.S., Nair, J.H., III, Jeck, G.A., and Smyth, H.F., Jr. (1956). The toxicity of butyl cellusolve solvent. AMA Arch. Ind. Health 14: 114-131.

Corley, R.A., Bormett, G.A., and Ghanayem, B.I. (1994). Physiologically-based pharmacokinetics of 2-butoxyethanol and its major metabolite 2-butoxyacetic acid, in rats and humans. Toxicol. Appl. Pharmacol. 129: 61-79.

Corley, R.A., Markham, D.A., Banks, C., Delorme, P., Masterman, A., and Houle, J.M. (1997). Physiologically based pharmacokinetics and the dermal absorption of 2-butoxyethanol vapor by humans. Fundam. Appl. Toxicol. 39: 120-130.

Corley, R.A., Bartels, M.J., Carney, E.W., Weitz, K.K., Soelberg, J.J., Gies, R.A., and Thrall, K.D. (2005). Development of a physiologically based pharmacokinetic model for ethylene glycol and its metabolite, glycolic acid, in rats and humans. Toxicol. Sci. 85: 476-490.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Dodd, D.E., Snellings, W.M., Maranpot, R.R., and Ballantyne, B. (1983). Ethylene glycol monobutyl ether. Acute, 9 day and 90 day vapor inhalation studies in Fischer 344 rats. Toxicol. Appl. Pharmacol. 68: 405-414.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances.

EU. (2006). European Union Risk Assessment Report on 2-Butoxyethanol (CAS No. 111-76-2), European Chemicals Bureau. Available at: https://echa.europa.eu/documents/10162/e74a38e1-b9e1-4568-92c5-615c4b56f92d.

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Heindel J.J., Gulati D.K., Russel V.S., Reel J.R., Lawton A.D. and Lamb J.C. (1990). Assessment of Ethylene Glycol Monobutyl and monophenol Ether reproductive toxicity using a continuous breeding protocol in Swiss CD-1 mice. Fundam. Appl. Toxicol. 15: 683-696.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Morrissey R.E., Lamb J.C., Schwetz B.A., Teague J.L. and Morris R.W. (1988). Association of sperm, vaginal cytology and reproductive organ weight data with results of continuous breeding reproduction studies in Swiss CD1 Mice. Fundam. Appl. Toxicol. 11: 359-371.

Morrissey R.E., Lamb J.C., Morris R.W., Chapin R.E., Gulati D.K. and Heindel J.J. (1989). Results and evaluations of 48 continuous breeding reproduction studies conducted in mice. Fundam. Appl. Toxicol. 13: 747-777.

National Toxicology Program [NTP]. (1993). Toxicity studies on ethylene glycol ethers administered in drinking water. NIH Publication 93- 3349. NTP Toxicity Report Series No. 26. NTP, Research Triangle Park, NC, USA.

National Toxicology Program [NTP]. (2000). Toxicology and Carcinogenesis Studies of 2-Butoxyethanol (CAS No. 111-76-2) in F344/N rats and B6C3F1 mice (Inhalation studies). NTP Technical Report Series No.484. NIH Publication No. 00-3974.

Nelson, B.K., Setzer, J.V., Brightwell, W.S., Mathinos, PR., Kuczuk, M.H., Weaver, T.E., and Goad, P.T. (1984). Comparative inhalation teratogenicity of four glycol ether solvents and an amino acid derivative in rats. Environ. Health Perspect. 57: 261-271.

Schuler R.L., Hardin B.D., Niemeier R.W., Booth G., Hazelden K., Piccirillo V. and Smith K. (1984). Results of testing 15 glycol ethers in a short term *in vivo* reprotoxicity assay. Environ. Health Perspect. 57: 141-146.

Sleet R.B., Price C.J., Marr M.C., Morrissey R.M. and Schwetz B.A. (1991). Cardiovascular development (CVD) in F-344 rats following phase-specific exposure to butoxy ethanol. Teratol. 43: 466.

Tyl, R.W., Millicovsky, G., Dodd, D.E., Pritts, I., France, K.A., and Fisher, L.C. (1984). Teratogenic evaluation of ethylene glycol monobutyl ether in Fischer 344 rats and new Zealand white rabbits following inhalation exposure. Environ. Health Perspect. 57: 47-68.

Udden, M.M. (2002). Rat erythrocyte morphological changes after gavage dosing with 2-butoxyethanol: a comparison with the in vitro effects of butoxyacetic acid on rat and human erythrocytes. J. Appl. Toxicol. 20: 381-387.

U.S. Environmental Protection Agency [EPA]. (2010). Toxicological Review of Ethylene Glycol Monobutyl Ether (EGBE) (CAS No. 111-76-2) in Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-08/006F. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0500tr.pdf

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Wier P.J., Lewis S.C., and Traul K.A. (1987). A comparison of developmental toxicity evident at term to postnatal growth and survival using ethylene glycol monoethyl ether, ethylene glycol monobutyl ether and ethanol. Teratog. Carcinog. Mutagen. 7: 55-64.

VINYLIDENE CHLORIDE/METHYLACRYLATE COPOLYMER

This dossier on vinylidene chloride/methylacrylate copolymer presents the most critical studies pertinent to the risk assessment of vinylidene chloride/methylacrylate copolymer in its use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): 1,1-dichloroethene; methyl prop-2-enoate

CAS RN: 25038-72-6

Molecular formula: $(C_2H_2Cl_2)_x(C_4H_6O_2)_y$ [This substance is a polymer.]

Molecular weight: 183.03 g/mol (monomer); polymer assumed to be > 1,000 g/mol (NICNAS, 2017)

Synonyms: vinylidene chloride/methylacrylate copolymer; methyl acrylate-vinylidene chloride copolymer; 2-propenoic acid, methyl ester, polymer with 1,1-dichloroethene

SMILES: COC(=O)C=C.C=C(Cl)Cl

II. PHYSICO AND CHEMICAL PROPERTIES

No chemical-specific information is available. Vinylidene chloride/methylacrylate copolymer is a non-ionic synthetic polymer. It is formed by addition polymerisation, which typically affords high molecular weight polymers with stable saturated carbon-chain backbones. Water solubility is expected to be low based on the predominantly hydrophobic structure of the substance.

As noted, no information is available regarding the molecular weight and the percentage of low molecular weight (LMW) species in this polymer. However, synthetic addition polymers of this type are generally high to very high molecular weight species. It is assumed for this polymer that the number average molecular weight (NAMW) is greater than 1,000 daltons (Da) with an insignificant percentage of LMW species (DoEE, 2017).

III. ENVIRONMENTAL FATE PROPERTIES

No experimental data are available for vinylidene chloride/methylacrylate copolymer.

Polymers with a molecular weight greater than 1,000 g/mol generally have a negligible vapour pressure, which indicates that the chemical is likely to exist solely as particulate matter in the atmosphere. As particulate matter, atmospheric oxidation is not expected to be a significant route of environmental removal. Likewise, volatilisation from water or moist soil is not expected to occur at an appreciable rate (USEPA, 2013).

Non-ionic polymers such as vinylidene chloride/methylacrylate copolymer are not expected to be highly soluble in water based on its predominantly hydrophobic structure. If

discharged to the aquatic environment, this polymer is expected to partition to soil or sediment. It is not expected to be highly mobile if released to the soil compartment (Boethling and Nabholz, 1997).

Synthetic non-ionic polymers are not expected to undergo rapid degradation (NICNAS, 2017). However, the high molecular weight of the polymer is expected to preclude or minimise bioaccumulation. Polymers with a number average molecular weight (NAMW) greater than 1,000 g/mol cannot cross biological membranes (Boethling and Nabholz, 1997).

IV. HUMAN HEALTH HAZARD ASSESSMENT

These polymers are considered chemically and biologically inert. As such, no toxicity studies have been conducted on this material.

NICNAS has assessed vinylidene chloride/methylacrylate copolymer in an IMAP Tier 1 assessment and considers it a polymer of low concern[1]. In addition, based on an assessment of human health and environmental hazards, NICNAS also identified vinylidene chloride/methylacrylate copolymer as a chemical of low concern to the environment (NICNAS, 2017 and DoEE, 2017). Chemicals of low concern are unlikely to have adverse environmental effects or be a concern to human health if they are released to the environment from coal seam gas operations.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No toxicological reference values or drinking water guidance values were developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Vinylidene chloride/methylacrylate copolymer does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Aquatic Toxicity

No ecotoxicity data was identified for vinylidene chloride/methylacrylate copolymer. Information on Non-Ionic Polymers Group (DoEE, 2017) is provided below.

> *"Non-ionic polymers with low water solubility, such as the methyl acrylate-vinylidene chloride copolymer, generally have low toxicity to aquatic life (Beothling and Nabholz 1997). Insoluble non-ionic polymers have low bioavailability and their adverse effects result from physical. effects such as*

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=25038-72-6

occlusion of respiratory organs (e.g. the gills of fish). These adverse effects occur only at very high loading levels in water (Beothling and Nabholz 1997).

Water soluble or dispersible non-ionic polymers, such as polyacrylamide, are also typically of low concern for ecotoxicity. Non-ionic polymers with NAMW greater than 1 000 cannot be absorbed across biological membranes in aquatic organisms, and therefore toxicity only occurs through indirect effects such as chelation of essential nutrients (Beothling and Nabholz 1997). However, the structure of polyacrylamide suggests that it will have low potential to act by this mode of action. This is further supported by median effective concentration (EC50) and median lethal concentration (LC50) values available for other water soluble or dispersible non-ionic polymers, which are greater than 100 mg/L (Beothling and Nabholz 1997).

Water soluble or dispersible polymers with NAMW less than 1 000 Da, or significant levels of LMW substances and trapped monomers, are of potential concern because of their increased bioavailability. However, this assessment was conducted assuming that the polymers in this group have NAMW greater than 1 000 Da and the percentage of LMW species is low."

B. Terrestrial Toxicity

No data are available.

C. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Vinylidene chloride/methylacrylate copolymer is not expected to be biodegradable. Thus, it meets the criteria for persistence.

Vinylidene chloride/methylacrylate copolymer is not expected to bioaccumulate. Polymers with a NAMW greater than 1,000 g/mol cannot cross biological membranes (Boethling and Nabholz, 1997). Thus, it does not meet the screening criteria for bioaccumulation.

No aquatic toxicity studies are available for vinylidene chloride/methylacrylate copolymer. It is expected to be a low concern of toxicity to aquatic organisms because of its low potential for bioavailability. Thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that vinylidene chloride/methylacrylate copolymer is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Burning produces harmful and toxic fumes. Heat from fire may melt, decompose polymer and generate flammable vapours. Combustion products may include: carbon oxides, hydrogen chlorine gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Potential combustible dust hazard. Avoid generating dust. Creates dangerous slipping hazard on any hard smooth surface.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid dust accumulation in enclosed space. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Electrostatic charge may build up during handling. Equipment, container and metal containers should be grounded and bonded.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Use adequate ventilation to avoid excessive dust accumulation. Store away from excessive heat and away from strong oxidising agents. Take measures to prevent the build-up of electrostatic charge.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure limit for vinylidene chloride/methylacrylate copolymer.

Engineering Controls

Use in a well-ventilated area. Avoid creating dust. Take precautionary measures against static charge.

Personal Protection Equipment

Respiratory Protection: Not normally needed; however, if significant exposures are possible, then the following respirator is recommended: Dust/mist respirator.

Hand Protection: Normal work gloves.

Skin Protection: Normal work coveralls.

Eye Protection: Wear safety glasses or goggles to protect against exposure.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Vinylidene chloride/methylacrylate copolymer is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

Boethling, R.S. and Nabholz, J.V. (1997). 'Environmental assessment of polymers under the US Toxic Substances Control Act', in Hamilton J and Sutcliffe R (eds), Ecological assessment of polymers: strategies for product stewardship and regulatory programs, Van Nostrand Reinhold, New York, USA, pp 187-234.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS (2017), Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

United States Environmental Protection Agency (USEPA). (2013). Interpretive Assistance Document for Assessment of Polymers: Sustainable Futures Summary Assessment. June 2013.

SILICON DIOXIDE

This dossier on silicon dioxide presents the most critical studies pertinent to the risk assessment of silicon dioxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on synthetic amorphous silica and silicates (OECD, 2004a,b), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

1 SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Silicon dioxide

CAS RN: 112926-00-8

Molecular formula: $nSiO_2$

Molecular weight: 60.08

Synonyms: Silicon dioxide; synthetic amorphous silica; silica gel; precipitated silica, crystalline-free

SMILES: O=[Si]=O

2 PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Silicon Dioxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Powder, granules, pellets	2	ECHA
Melting Point	1,713°C	2	ECHA
Boiling Point	2.2 g/cm^3	2	ECHA
Water Solubility	76 – 128 mg/L* (slightly soluble)	1	ECHA

*Based on dissolved SiO_2.

3 ENVIRONMENTAL FATE PROPERTIES

A. Summary

Silicon oxides are the most abundant compounds in the earth's crust mass. Silicon dioxide (CAS No. 112926-00-8) released into the environment is expected to combine indistinguishably with the soil layer or sediment due to their chemical similarity with inorganic soil matter (OECD, 2004a).

Biodegradation is not applicable to silicon dioxide (CAS No. 112926-00-8). The bioavailable form of silicon dioxide (CAS No. 112926-00-8) is the dissolved form which exists exclusively

as monosilicic [$Si(OH)_4$] acid under environmental pH (OECD, 2004a). Although the water-soluble fraction of silicon dioxide (CAS No. 112926-00-8) acts as weak acid, pH changes are not likely to occur in the environment due to low aquatic releases and sufficient natural buffer capacities (OECD, 2004a).

Bioaccumulation of silicon dioxide (CAS No. 112926-00-8) is generally unlikely to occur. However, dissolved silica can be actively assimilated by some marine and terrestrial organisms as normal natural processes mainly related to structural function.

4 HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The oral bioavailability of silicon dioxide in animals and humans is low. Absorbed silicon dioxide is rapidly eliminated and there is no accumulation in the body. The bioavailability of silicon dioxide by the inhalation route is low. While there is deposition in the lungs following inhalation exposure to silicon dioxide, it is rapidly eliminated. The acute toxicity of silicon dioxide is low by the oral, inhalation and dermal routes. Silicon dioxide is not irritating to the skin and eyes. Repeated oral exposures to rodents showed no adverse effects. Repeated inhalation exposure to high respirable levels of silicon dioxide resulted in an inflammatory response in the respiratory tract and lungs, which was reversible following cessation of exposure. Silicon dioxide is not genotoxic. Although the study was of poor quality, there was no evidence of adverse effects on reproduction in rats given silicon dioxide in the diet. Animal studies showed no adverse effects on foetal development from oral exposure to silicon dioxide.

B. Toxicokinetics/Metabolism

The oral bioavailability of silicon dioxide in animals and humans is low. Absorbed silicon dioxide is rapidly eliminated and there is no accumulation in the body. The bioavailability of silicon dioxide by the inhalation route is low. While there is deposition in the lungs following inhalation exposure to silicon dioxide, it is rapidly eliminated (OECD, 2004a,b).

C. Acute Toxicity

The oral LD_{50} of silicon dioxide (CAS No. 112926-00-8) in rats from two different studies is >5,000 mg/kg (ECHA) [Kl. scores = 1].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112926-00-8) is >0.69 mg/L, which was the maximum technically attainable concentration. The mass median aerodynamic diameter (MMAD) was approximately 0.6 µm, and approximately 65% of the mass was <6 µm (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112945-52-5) is >2.08 mg/L. The MMAD was approximately 0.76 µm, and approximately 98-99.4% of the mass was <10 µm (ECHA) [Kl. score = 2].

The 4-hour inhalation LC_{50} in rats for an aerosol of silicon dioxide (CAS No. 112945-52-5) from a nose-only exposure is >0.14 mg/L, which was the maximum technically attainable concentration. The MMAD was 3.2 µm, and 47-50% of the mass was <6 µm (ECHA) [Kl. score = 2].

The dermal LD_{50} in rabbits is >5,000 mg/kg (no deaths) (ECHA) [Kl. score = 2].

D. Irritation

Application of 0.5 g silicon dioxide (CAS No. 112926-00-8) to the skin of rabbits for 4 hours under occlusive conditions was not irritating (ECHA) [Kl. score = 1].

Instillation of 0.1 g silicon dioxide (CAS No. 112926-00-8) to the eyes of rabbits was minimally irritating (ECHA) [Kl. score = 1].

E. Sensitisation

No studies are available.

F. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given diets containing silicon dioxide (CAS No. 112926-00-8) for 90 days. The dietary concentrations as silica concentrations were 0, 0.4-0.7, 1.7-1.9 or 6.5-7.0% silica; this equates to 0, 300-330, 1,200-1,400 or 4,000-4,500 mg/kg CAS No. 112926-00-8. There were no treatment-related effects. The NOAEL is 4,000 to 4,500 mg/kg-day (ECHA) [Kl. score = 1].

Male and female CD rats were given diets containing silicon dioxide (CAS No. 112926-00-8) for 6 months. The estimated daily intakes were 0, 2,170 and 7,950 mg/kg-day for males, and 0, 2,420 and 8,980 mg/kg-day for females. There were no treatment-related effects. The NOAEL is 7,950 and 8,980 mg/kg-day for males and females, respectively (ECHA) [Kl. score = 1].

Male and female Fischer 344 rats were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 102 weeks. The dose levels were 0, 12,500, 25,000 and 50,000 ppm. There were no treatment-related effects on body weight gain, feed consumption, survival, or hematology parameters. Liver weights were lower (up to 15%) in the ≥25,000 ppm females from 12 to 24 months; a dose-related trend was not apparent. The NOAEL is 50,000 ppm. Using a body specific food consumption rate, the NOAEL corresponds to 2,500 mg/kg-day (ECHA) [Kl Score = 2].

Male and female $B6C3F_1$ mice were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 93 weeks. The dose levels were 0, 12,500, 25,000 and 50,000 ppm. There were no treatment-related effects on survival or clinical signs. Body weight gain was lower in the 5% group from week 15 to week 50 for the males and from 30 to 50 for the females. Mean body weights for 5% group animals for the remainder of the study were similar to controls. The NOAEL is 50,000 ppm in the diet. Using 0.13 as the fraction of body weight that mice consume per day as food (U.S. EPA), the NOAELs corresponds to 6,500 mg/kg-day (ECHA) [Kl Score = 2].

Inhalation

Male and female Wistar rats were exposed by inhalation to 0, 1, 6 or 30 mg/m^3 silicon dioxide (CAS No. 112945-52-5) 6 hours/day, 5 days/week for 13 weeks. There were no

deaths during the study. Respiration rates were increased in a concentration-dependent manner. Body weight and body weight gain were unaffected in females, but were lower in the males with the 30 mg/m^3 groups significantly affected throughout the study. At ≥6 mg/m^3, there were haematological changes, increased lung weights and histopathologic changes in the lungs (including collagen increase and sporadic focal fibrosis). At 1 mg/m^3, there was a slight, but fully reversible, pulmonary response indicative of an inflammatory reaction. The NOAEC for this study is 1.3 mg/m^3 (ECHA) [Kl. score = 1].

Dermal

No adequate studies are available.

G. Genotoxicity

In Vitro Studies

The results of *in vitro* genotoxicity studies on silicon dioxide are presented below in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Silicon Dioxide

Test System	Test substance	Results*		Klimisch Score	Reference
		-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	CAS No. 112926-00-8	-	-	2	Prival *et al.* (1991)
Bacterial reverse mutation (*E. coli* strains)	CAS No. 112926-00-8	-	-	2	Prival *et al.* (1991)
Bacterial reverse mutation (*S. typhimurium* strains)	CAS No. 112945-52-5	-	-	1	ECHA
Mammalian cell gene mutation (CHO cells)	CAS No. 112945-52-5	-	-	1	ECHA
Chromosomal aberration (Human embryonic lung cells, WI-38)	CAS No. 112926-00-8	NA	-	2	ECHA
Chromosomal aberration (CHO cells)	CAS No. 112945-52-5	-	-	1	ECHA
Unscheduled DNA synthesis (primary rat hepatocytes)	CAS No. 112945-52-5	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable.

In Vivo Studies

Male F344 rats were exposed by inhalation to 0 or 50 mg/m^3 silicon dioxide (CAS No. 112945-52-5) 6 hours/day, 5 days/week for 13 weeks. When tested in a HPRT assay, there was no increase in mutation frequency in the alveolar Type II cells from exposed rats compared to controls (ECHA) [Kl. score = 2].

Male SD rats were given by oral gavage either a single dose of 0, 1,4, 14, or 140 mg/kg silicon dioxide (CAS No. 112926-00-8), or five consecutive daily doses of 0, 500, or 5,000 mg/kg

silicon dioxide (CAS No. 112926-00-8). Chromosomal aberrations were not significantly increased in the treated animals compared to controls (ECHA) [Kl. score = 2].

In a dominant lethal mutation assay, male SD rats were given by oral gavage either a single dose of 0, 1, 4, 14 or 140 mg/kg silicon dioxide (CAS No. 112926-00-8), or five consecutive daily doses of 0, 500, or 5,000 mg/kg silicon dioxide (CAS No. 112926-00-8). There was no indication of a mutagenic effect by silicon dioxide (CAS No. 112926-00-8) (ECHA) [Kl. score = 2].

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 102 weeks. The dose levels were 0, 12,500, 25,000 and 50,000 ppm. The incidence of tumours was similar between treated and control animals. The number of animals used in this study was small (ECHA) [Kl Score = 2]. Male and female $B6C3F_1$ mice were fed a diet containing a synthetic amorphous silica (CAS No. not stated) for 93 weeks. The incidence of tumours was similar between treated and control animals (ECHA) [Kl Score = 2].

I. Reproductive Toxicity

A one-generation reproductive toxicity study has been conducted on silicon dioxide (CAS No. 112945-52-5). Male and female Wistar rats were given diets containing 0 or 497 mg/kg-day (males) or 509 mg/kg-day (females). In the parental animals, there were no treatment-related effects on mortality, clinical symptoms, feed consumption, body weight gain and measured hematology parameters. There was no reproductive or developmental toxicity (ECHA) [Kl. score = 3].

J. Developmental Toxicity

Pregnant female rats were given by oral gavage doses up to 1,350 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,350 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female mice were given by oral gavage doses up to 1,340 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,340 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female rabbits were given by oral gavage doses up to 1,600 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female Syrian hamsters were given by oral gavage up to 1,600 mg/kg silicon dioxide (CAS No. 112926-00-8) on GD 6-10. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 1,600 mg/kg-day, the highest dose tested (ECHA) [Kl. score = 2].

5 DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for silicon dioxide (CAS No. 112945-00-8) follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

There were no adverse effects seen in rats or mice fed a diet containing up to 50,000 ppm silicon dioxide (CAS No. not stated) for 102 and 93 weeks, respectively (Takizawa *et al.*, 1988). The NOAELs for rats and mice were 2,500 and 6,500 mg/kg-day, respectively. The lowest NOAEL of 2,500 mg/kg-day will be used for determining the oral Reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:
UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1

Oral RfD = 2,500/(10 x 10 x 1 x 1 x 1) = 2,500/100 = 25 mg/kg-day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2L (ADWG, 2011)

Drinking water guidance value = (25 x 70 x 0.1)/2 = 88 mg/L

B. Cancer

Silicon dioxide was not carcinogenic to rats or mice in chronic dietary studies. Hence, a cancer reference value was not derived.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Silicon dioxide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

7 ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Silicon dioxide has a low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on silicon dioxide.

Table 3: Acute Aquatic Toxicity Studies on Silicon Dioxide

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-h LL_0	10,000*	1	ECHA
Danio rerio	96-h LL_0	10,000	1	ECHA
Daphnia magna	48-h EL_{50}	>1,000**	2	ECHA
Daphnia magna	24-h EL_{50}	>10,000	2	ECHA

*Silica, amorphous, fumed, crystalline-free (CAS No. 112945-52-5)

**Mortality may have occurred from physical effects of unfiltered medium.

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for silicon dioxide follow the methodology discussed in DEWHA (2009).

PNEC water

Silicon dioxide is a solid in powder form, which is slightly soluble in water. Acute aquatic toxicity studies on fish and *Daphnia* using excess loadings of silicon dioxide showed no acute toxicity (Table 3). Physical effects of silicon dioxide on *Daphnia* were seen in tests using unfiltered test medium (OECD, 2004a,b; ECHA). Because of the physico-chemical properties of silicon dioxide, the $PNEC_{water}$ was not determined.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The $PNEC_{sed}$ cannot be derived using the equilibrium partitioning method.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. The $PNEC_{soil}$ cannot be derived using the equilibrium partitioning method.

8 PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REAC Criteria methodology (DEWHA, 2009; ECHA, 2008).

Silicon dioxide (CAS No. 111945-00-8) released into the environment is expected to combine indistinguishably with the soil layer or sediment due to their chemical similarity with inorganic soil matter. Biodegradation is not applicable to silicon dioxide (CAS No. 112926-00-8). For the purposes of this PBT assessment, the persistent criteria is not considered applicable to silicon dioxide (CAS No. 112926-00-8).

Silicon dioxide (CAS No. 112926-00-8) is an inorganic substance that is a slightly soluble powder. Bioaccumulation of silicon dioxide (CAS No. 112926-00-8) is generally unlikely to occur, given its low bioavailability. However, dissolved silica can be actively assimilated by some marine and terrestrial organisms as normal natural processes mainly related to structural function. For the purposes of this PBT assessment, silicon dioxide (CAS No. 112926-00-8) does not meet the criteria for bioaccumulation.

The acute toxicity of the water-soluble fraction of silicon dioxide (CAS No. 112926-00-8) is >1 mg/L. Thus, it does not meet the criteria for toxicity.

The overall conclusion is that silicon dioxide (CAS No. 112926-00-8) is not a PBT substance.

9 CLASSIFICATION AND LABELLING

A. Classification

No classified.

B. Labelling

No signal word.

C. Pictogram

None.

10 SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

No data are available.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for silica gel (silicon dioxide, CAS No. 112926-00-8) in Australia is 10 mg/m^3 as an 8-hour TWA.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Use respiratory protection if airborne dust levels are expected to exceed the occupational exposure guidance value.

Hand Protection: Use gloves.

Skin *Protection*: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Silicon dioxide is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

11 DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

12 REGULATORY STATUS

Australian AICS Inventory: Listed.

13 REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2004a). Screening Information Dataset (SIDS) Initial Assessment Report for Synthetic Amorphous Silica and Silicates: Silicon Dioxide (CAS No. 7631-86-9, 112945-52-5, 112926-00-8; Silicic Acid, Aluminum Sodium Salt (CAS No. 1344-00-9); Silicic Acid, Calcium Salt (CAS No. 1344-95-2), UNEP Publications.

OECD (2004b). IUCLID Data Set for Synthetic Amorphous Silica and Silicates: Silicon Dioxide (CAS No. 7631-86-9, 112945-52-5, 112926-00-8; Silicic Acid, Aluminum Sodium Salt (CAS No. 1344-00-9); Silicic Acid, Calcium Salt (CAS No. 1344-95-2), UNEP Publications.

Prival, M.J., Simmon, V.F., and Mortelmans, K.E. (1991). Bacterial mutagenicity testing of 49 food ingredients gives very few positive results. Mutat. Res. 260: 321-329.

CRYSTALLINE SILICA, QUARTZ (CAS NO. 14808-60-7)
CRYSTALLINE SILICA, CRISTOBALITE (CAS NO. 14464-46-1)
CRYSTALLINE SILICA, TRIDYMITE (CAS NO. 15468-32-3)
NON-CRYSTALLINE SILICA (IMPURITY) (CAS NO. 7631-86-9)
DIATOMACEOUS EARTH (CAS NO. 61790-53-2)
DIATOMACEOUS EARTH, CALCINED (CAS NO. 91053-39-3)

This dossier on crystalline silica, quartz, cristobalite and tridymite; non-crystalline silica (impurity); diatomaceous earth; and diatomaceous earth, calcined presents the most critical studies pertinent to the risk assessment of these substances in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

For the purpose of this dossier, crystalline silica, quartz (CAS No. 14808-60-7) has been reviewed as representative of crystalline silica cristobalite and tridymite, and non-crystalline silica (impurity). Crystalline silica, quartz is also considered representative of diatomaceous earth and diatomaceous earth, calcined, as they both consist mainly of silicon dioxide.

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dioxosilane

CAS RN: 14808-60-7

Molecular formula: SiO_2

Molecular weight: 60.084 g/mol

Synonyms: Cristobalite, Dioxide, Silicon

SMILES: O=[Si]=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Silica is an off-white granule that occurs naturally in various crystalline and amorphous or other non-crystalline forms. Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. Other crystalline forms of silica include cristobalite, tripoli and tridymite. Particle size is a key determinate of silica toxicity, since toxicity is restricted to particles that are small enough to be deposited into the target regions of the respiratory tract (OECD, 2011).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. It is a stable solid under typical environmental conditions. It will not biodegrade, bioaccumulate, nor will it sorb to sediments or soils.

B. Biodegradation

No data are available. Based on the crystalline form of the substance, it is not expected to biodegrade.

C. Environmental Distribution

No experimental data are available for crystalline silica. As a stable inorganic solid, it is not soluble in water, and it will not sorb to soils or sediment.

D. Bioaccumulation

There are no bioaccumulation studies on crystalline silica.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Human exposure to crystalline silica via inhalation can lead to silicosis, lung cancer and pulmonary tuberculosis (WHO, 2000).

B. Acute Toxicity

No adequate acute oral, dermal or inhalation exposure studies are available for quartz, cristobalite or tridymite.

Most acute toxicity studies for quartz or cristobalite were conducted using intratracheal instillation. Intratracheal instillation is the introduction of the substance directly to the trachea and is used to test respiratory toxicity of a substance.

Single intratracheal instillation of quartz caused inflammatory effects and formation of discrete silicotic nodules in rats, mice and hamsters (IARC, 2012; WHO, 2000). Other effects like oxidative stress, cellular proliferation and increases in water, protein and phospholipid content of rat lungs, apoptosis (programmed cell death) and lung cancer were also noted.

In an acute dose study, rats were dosed once with 0, 0.75, 1.5, 3.0, 6.0 or 12 mg/kg bw/day quartz by intratracheal instillation (Seiler et al., 2001). The lowest observed adverse effect level (LOAEL) of 0.75 mg/kg bw/day was derived from these studies.

Two other similar studies of single intratracheal instillation of quartz reported higher LOAELs in rats (3 and 40 mg/kg bw/day) based on inflammation and fibrosis (Saffiotti et al., 1996).

C. Irritation

No data available.

D. Sensitisation

No data available.

E. Repeated Dose Toxicity

Oral

No data available.

Inhalation

Repeated inhalation exposure of crystalline is known to cause adverse effects (IARC, 2012). Silicosis has been identified as the main non-cancer effect of silica exposure, although available epidemiologic data as well as animal data provide evidence for several other effects associated with silica exposure, such as silicotuberculosis, enlargement of the heart (cor pulmonale), interference with the body's immune system and damage to the kidneys (Health Canada, 2013).

Dermal

No data available.

F. Genotoxicity

No data available.

G. Carcinogenicity

Oral

No data available.

Inhalation

The International Agency for Research on Cancer (IARC) has classified crystalline silica as a Group 1 carcinogen, as there was sufficient evidence for carcinogenicity in experimental animals and sufficient evidence for carcinogenicity of inhaled crystalline silica from occupational sources (IARC, 1997; IARC, 2012).

H. Reproductive Toxicity

No data available.

I. Developmental Toxicity

No data available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on crystalline silica is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Crystalline silica does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Although no data are available, crystalline silica is expected to exhibit low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

No aquatic toxicity data were available.

C. Terrestrial Toxicity

No terrestrial toxicity data were available.

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Crystalline silica is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to crystalline silica.

As an inorganic complex it is not expected to bioaccumulate. Thus, crystalline silica does not meet the screening criteria for bioaccumulation.

Crystalline silica is not expected to cause adverse effects in environmental receptors. Thus, this substance does not meet the screening criteria for toxicity.

Therefore, crystalline silica is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

H373 – may cause damage to organs through prolonged or repeated exposure.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention if symptoms persist.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Get medical attention if respiratory irritation develops or breathing becomes difficult.

Ingestion

Rinse mouth. Do not induce vomiting. Get medical attention if symptoms occur.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use extinguishing media appropriate for surrounding material.

Specific Exposure Hazards

Reacts with hydrofluoric acid (HF) forming toxic gas (SiF_4).

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Pick up mechanically – vacuum up. Avoid generating dust. If formation of dust cannot be avoided, use respiratory filter device. Dispose of the material collected according to regulations.

D. Storage And Handling

General Handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes, skin and clothing. Avoid dust formation. Do not breathe dust. Wash thoroughly after handling. Use with adequate ventilation.

Storage

Provide adequate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits. Keep containers tightly closed in a dry, cool, well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has established an occupational exposure standard for exposure to crystalline silica of an 8-hour time weighed average (TWA) exposure limit of 0.05 mg/m^3.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls

to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; as well as before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Crystalline silica is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Health Canada. (2013). Environment Canada, Health Canada. Screening Assessment for the Challenge: Quartz (CAS 14808-60-7) and Cristobalite (CAS 14464-46-1). June 2013. https://www.ec.gc.ca/ese-ees/1EB4F4EF-88EE-4679-9A6C-008F0CBC191C/FSAR_B12%20-%2014464-46-1%20%26%2014808-60-7%20%28QC%29_EN.pdf

IARC. (1997). Silica, some silicates, coal dust and Para-aramid fibrils. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 15-22 October 1996. IARC Monogr Eval Carcinog Risks Hum. 1997;68:1–475.

IARC. (2012). Silica dust, crystalline, in the form of quartz or cristobalite. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 17-24 March, 2009. IARC Monogr Eval Carcinog Risks Hum. 2012;100C:355–405

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2011). OECD -SIDS Initial Targeted Assessment Profile on Quartz and Cristobalite, SIAM 32, 19-21 April 2011. https://hpvchemicals.oecd.org/ui/handler.axd?id=b68bb357-e6dd-4db9-b05c-8148223fc0ff.

Saffiotti, U., Williams, O., Lambert, N., Daniel, N., Kaighn, M.E., Mao, Y., Shi, X. (1996). Carcinogenesis by crystalline silica: animal, cellular, and molecular studies. In:Castranova V, Vallyathan V, Wallace WE, eds. Silica and silica-induced lung diseases. Boca Raton, FL, CRC Press, pp. 345–381.

Seiler, F., Rehn, B. and Bruch, J. (2001). Evidence of a no-effect level in silica–induced rat lung mutagenicity but not in fibrogenicity. Archives of Toxicology 74: 716-719.

WHO. (2000). Concise International Chemical Assessment Document 24 - Crystalline Silica, Quartz. Produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals. WHO Geneva.

CHOLINE CHLORIDE

This dossier on choline chloride (CAS RN 67-48-1) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on choline chloride (OECD, 2004), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-hydroxy-N,N,N-trimethylethanaminium chloride

CAS RN: 67-48-1

Molecular formula: $C_5H_{14}NO.Cl$

Molecular weight: 139.6 g/mol

Synonyms: Choline chloride; 2-hydroxy-N,N,N-trimethylethanaminium chloride; trimethyl(2-hydroxyethyl)ammonium chloride; cholinium chloride; 2-hydroxyethyl(trimethyl)azanium chloride

SMILES: C[N+](C)(C)CCO.[Cl-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Choline Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	White crystalline solid*	2	OECD (2004)
Melting Point	~ 200°C @ 101.3 kPa	1	ECHA
Boiling Point	Decomposition at 305°C @ 101.3 kPa prior to boiling	2	ECHA
Density	70% aq. solution: 1110 kg/m^3@ 20°C	4	OECD (2004)
Partition Coefficient (log K_{ow})	75% aq. solution: -3.77 @ 25°C	1	ECHA
Vapour Pressure	2287.2 Pa @ 25°C (QSAR)	2	ECHA
Water Solubility	Powder containing 50% choline chloride: 650 g/L (temperature unknown	4	OECD (2004)
Auto flammability	330°C	2	ECHA

Property	Value	Klimisch score	Reference
Viscosity	75% aq. solution: 26.2 mPa.s @ 20°C; 14.1 mPa.s @ 40°C	1	ECHA
Henry's Law Constant	2.06 x 10-11 Pa.m^3/mol @ 25 °C (estimated using HENRYWIN v3.10)	-	OECD (2004)

*Choline chloride is a white crystalline solid; it is marketed as an aqueous solution (70-75% w/w in water), which is colourless with an amine-like odour.

Choline chloride is a quaternary amine salt that will dissociate in water into choline ($C_5H_{14}NO^+$) ions and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

A. Partitioning

Choline chloride is highly water soluble and non-volatile. When released to water under typical environmental conditions, the quaternary ammonium salt dissociates to release a positively charged choline ion and a negatively charged chloride ion (OECD, 2004). It is unlikely to partition to the atmosphere based on its low volatility (OECD, 2004).

B. Biodegradation

Choline chloride is readily biodegradable (93% within 14 days) in a MITI-I test (MITI, 1992; OECD, 2004). In another MITI-I test, biodegradation was $\geq$60%, indicating ready biodegradation (Tunkel *et al.*, 2000; OECD, 2004). A $BOD_5/ThOD_5$ ratio of 75% was obtained in a BOD_5 test performed according to DIN 38409 part 43 (BASF AG, 1984; OECD, 2004).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

No experimental data are available for choline. Choline is a quaternary ammonium compound (QAC); these compounds are not included in the training set for the K_{oc} estimation of the QSAR model KOCWIN v. 2.00 in EPISuite™ (USEPA, 2016), and therefore outside the program's prediction domain. A K_{oc} value of 2.3 had been estimated using the older QSAR model PCKOCWIN v. 1.66 (OECD, 2004), indicating a low potential for soil adsorption.

Results from Mackay Level I modelling indicate that choline chloride will be distributed completely into water (OECD, 2004).

D. Bioaccumulation

No measured data on bioaccumulation of choline chloride is available. An experimental log K_{ow} is -3.77, which indicates a low potential to accumulate in organisms (OECD, 2004). Bioaccumulation is not expected in aquatic organisms.

E. Summary

Choline chloride is readily biodegradable. Distribution modelling using Mackay Level 1 shows choline to be distributed completely into water. Choline chloride will not adsorb on soil and sediments. It is not expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Choline is a vitamin-like essential nutrient. It has low acute toxicity by the oral route and is slightly irritating to the skin and eyes. Repeated high intake of choline in humans has been reported to cause a slight hypotensive effect. No adverse effects (including tumours) were seen in rats given choline in the diet for 72 weeks. Choline is not genotoxic. High dietary doses of choline to pregnant mice resulted in developmental toxicity (but no teratogenic effects) at levels that were maternally toxic.

NICNAS has assessed fumaric acid in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Metabolism

Choline is a vitamin-like essential nutrient. Although the body can synthesise choline in small amounts, it is insufficient to maintain health and must be consumed in the diet. Choline is required for the synthesis of phospholipids in cell membranes, methyl group metabolism and acetylcholine synthesis (neurotransmitter) (Zeisel and Blusztajn, 1994).

Dietary choline is taken up into the body by transporter proteins present in the cells lining the small intestine (IOM, 2000). In the small intestine, prior to uptake into the small intestinal cells, some choline is metabolised by bacteria to betaine and methylamines (Zeisel et al., 1980). Dietary choline can be present as free choline or in esterified forms (i.e., phosphocholine, glycerophosphocholine, sphingomyelin, and phosphatidylcholine) (Zeisel and Blusztain, 1994). Free choline is formed from these esterified choline compounds by pancreatic enzymes.

Choline is involved in a number of biochemical pathways in eukaryotic and prokaryotic cells. It is a precursor for acetylcholine (a neurotransmitter); phospholipids (structural integrity and signaling roles for cell membranes); and a major source for methyl groups (IOM, 2000).

C. Acute Toxicity

<u>Oral</u>

The oral LD_{50} values of choline in rats are approximately 3,500 and 5,500 mg/kg (ECHA) [Kl. scores = 2].

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 110-17-8%2C+

Inhalation

No acute inhalation or dermal toxicity studies are available.

D. Irritation

Skin

Application of a 70% aqueous solution to the skin of rabbits for 20 hours under occlusive conditions resulted in ambiguous skin irritation (BASF AG, 1963a; OECD, 2004) [Kl. score = 2].

Eye

Slight eye irritation was seen in the eyes of rabbits after instillation of a 70% aqueous solution of choline chloride; no effects were seen 24 hours after exposure (BASF AG, 1963b; OECD, 2004) [Kl. score = 2].

E. Sensitisation

No data are available in animals. In a Human Repeated Insult Patch Test (HRIPT), there was no evidence of dermal sensitisation in 200 subjects given 0.5% (w/v) aqueous solution of choline chloride during the induction phase and 0.2% (w/v) aqueous solution during the challenge phase (Colgate-Palmolive, 2003; OECD, 2004).

F. Repeated Dose Toxicity

Oral

A 72-week feeding study was conducted to investigate the impact of choline chloride on the liver tumour promoting activity of phenobarbital and DDT in diethylnitroamine-initiated Fischer 344 rats. Animals received approximately 500 mg/kg/day choline chloride. Following the end of the exposure period, the animals were kept on the same untreated diet as the control group until study termination at week 103. Histopathology was limited to the liver and organs that developed gross abnormalities. There were no significant differences between treated and control animals on survival rates, body weights, and relative liver weights. There were no increased number of neoplastic liver nodules, hepatocellular carcinomas, lung tumours, leukemia or other tumours between treated and control animals. The NOAEL for choline chloride in this study is 500 mg/kg-day (Shivapurkar *et al.*, 1986) [Kl. score = 3].

In humans, oral administration of 10,000 mg/day choline chloride in a pilot study treating a small number of patients with Alzheimer's disease resulted in a slight hypotensive effect (Boyd *et al.*, 1977). This dose was regarded as a LOAEL by the U.S. Institute of Medicine (IOM) Standing Committee on the Scientific Evaluation of Dietary Reference Intake (2000).

Inhalation

No adequate or reliable studies are available.

Dermal

No adequate or reliable studies are available.

G. Genotoxicity

In Vitro Studies

Choline chloride was not mutagenic to bacteria in reverse mutation assays (Haworth *et al.*, 1983, Litton Bionetics, 1977).

A small, but statistically significant, and dose-related increase in chromosomal aberrations was reported in Chinese Hamster Ovary (CHO) cells at doses of 50 and 500 µg/mL choline chloride in the absence of S9 only (Bloom *et al.*, 1982). No higher concentrations were examined. These results could not be confirmed in two studies using CHO cells at concentrations of choline chloride up to 5,000 µg/mL (Galloway *et al.*,1985).

In sister chromatid exchange (SCE) assays, ambiguous results were obtained in two parallel studies (at two different laboratories) in CHO cells at concentrations up to 50 and 5,000 µg/mL choline chloride, respectively. Cytotoxicity was observed at 5,000 µg/mL. In laboratory 2, the increase in SCEs, which was sporadic and not dose-related, that was observed with metabolic activation was not reproduced in laboratory 1. Laboratory 1 showed a weak positive at the top dose without metabolic activation, but a comparison with laboratory 2 was not possible due to the insufficient number of cells analysed (Bloom *et al.*, 1982; Galloway *et al.*, 1985).

Choline chloride was negative in a gene conversion assay with *Saccharomyces cerevisiae* strain D4 in the presence or absence of metabolic activation (Litton Bionetics, 1977; OECD, 2004).

In Vivo Studies

No studies are available.

H. Carcinogenicity

Oral

No studies are available.

Inhalation

No studies are available.

I. Reproductive Toxicity

No reliable studies have been conducted that address female fertility or reproductive toxicity by a relevant route of exposure.

J. Developmental Toxicity

Oral

Pregnant female mice were given in their feed 0, 1, 2.5, 5, or 10% choline chloride (0 or approximately 1,250, 4,160, 10,800, or 20,000 mg/kg choline chloride) on gestational days 1 to 18. Maternal body weight gain was reduced in all treated groups except for the 1,250

mg/kg group. Maternal weight gain of dams with embryonic/foetal absorptions showed no net weight gain at >4,160 mg/kg, but there was net weight loss in the 20,000 mg/kg group. All foetuses were resorbed in the 20,000 mg/kg group. Embryonic/foetal lethality of 35% and 69% were seen in the 4,160 and 10,800 mg/kg groups, respectively. No resorptions occurred in the 1,250 mg/kg group. Developmental toxicity was seen at >4,160 mg/kg group. There were no statistically significant increases in malformations in any dose group. The NOAEL for maternal and developmental toxicity is 1,250 mg/kg/day (BASF AG, 1966; OECD, 2004) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for choline chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The Standing Committee on the Scientific Evaluation of Dietary Reference Intakes selected hypotension as the critical effect from the study by Boyd *et al.* (1977) when deriving a Tolerable Upper Intake Level. Boyd *et al.* (1977) reported a LOAEL of 10,000 mg/day choline chloride (7,500 mg/day choline). An uncertainty factor of 2 was chosen because of the limited data regarding hypotension and the inter-individual variation in response to cholinergic effects. Thus, the value for the Tolerable Upper Intake Level or repeated exposure of adults to choline is 3,500 mg/day choline.

Note that the Australian National Health and Medical Research Council (2014) concluded that there are no data to suggest that there is increased susceptibility to choline during pregnancy or lactation; thus, the upper level of intake choline is the same for women during pregnancy or lactation as it is for adults (3,500 mg/day choline).

Oral Reference Dose (oral RfD)

An oral RfD for choline is derived as follows: the LOAEL of 7,500 mg/day from the Boyd *et al.* (1977) study is divided by an uncertainty factor of 2 to obtain a value of 3,500 mg choline/day or 50 mg choline/kg/day for a 70 kg person.

Oral RfD = 50 mg/kg/day [choline]

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (50 x 70 x 0.1)/2 = 175 mg/L [choline]

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2021).

B. Cancer

There are no carcinogenicity studies on choline chloride. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Choline chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Choline chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on choline chloride.

Table 2: Acute Aquatic Toxicity Studies on Choline Chloride

Test Species	Endpoint	Results (mg/L)[1]	Klimisch score	Reference
Oryzias latipes	96-hour LC_{50}	>100 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)
Leuciscus idus	96-hour LC_{50}	>10,000*	2	OECD (2004); ECHA
Daphnia magna	48-hour EC_{50}	349 (nominal and measured)	2	MOE Japan (1999b); OECD (2004)
Daphnia magna	48-hour EC_{50}	>500*	2	OECD (2004)
Pseudokirchneriella subcapitata	72-hour EC_{50}	>1,000 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)

*78% aqueous solution of choline chloride

Chronic Studies

In a 21-day *Daphnia magna* reproduction test, the nominal and measured NOEC was reported to be 30.2 mg/L (MOE Japan, 1999d) [Kl. score = 1].

The NOEC from a 72-hr algae *Pseudokirchneriella subcapitata* study is 30.2 mg/L (MOE Japan, 1999c; OECD, 2004) [Kl. score = 1].

C. Terrestrial Toxicity

No data is available.

Choline is present in all plant and animal cells, mostly in the form of phospholipids (phosphotidylcholine or lecithin, lysophosphatidylcholine, choline plasmalogens and sphingomyelin), which are essential components of membranes (IOM, 2000).

D. Calculation of PNEC

The PNEC calculations for choline chloride follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (>100 mg/L), invertebrates (349 mg/L) and algae (>1,000 mg/L). Results from chronic studies are available for invertebrates (21-day NOEC = 30.2 mg/L) and algae (72-hour NOEC = 32 mg/L). On the basis that the data consists of chronic studies on two trophic level (albeit not on the species with the lowest $E(L)C_{50}$), an assessment factor of 100 has been applied to the lowest reported NOEC of 30 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 0.3 mg/L (0.22 mg/L for choline).

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.15 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1{,}000 \times PNEC_{water}$
$= (0.844/1280) \times 1{,}000 \times 0.22$
$= 0.15$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1{,}000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.092/1{,}000 \times 2400]$
$= 0.844\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 2.3 x 0.04

= 0.092 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ for choline is 0.007 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1{,}000 \times PNEC_{water}$

= (0.05/1500) x 1,000 x 0.22

= 0.007 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 2.3 x 0.02

= 0.05 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Choline chloride is readily biodegradable and thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -3.77, choline chloride does not meet the criteria for bioaccumulation.

The NOEC values from chronic toxicity studies on choline chloride are >0.1 mg/L. Thus, choline chloride does not meet the criteria for toxicity.

The overall conclusion is that choline chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, nitrogen oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Choline chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Australian National Health and Medical Research Council (2014). Nutrient Reference Values for Australia and New Zealand: Choline. Accessed at: https://www.nrv.gov.au/nutrients/choline

BASF AG (1963a). Toxicity of choline chloride 70 % in water; skin irritation after exposure to choline chloride. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1963b). Toxicity of choline chloride 70% in water; eye irritation. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1966). Study on teratogenic effects of choline chloride in the mouse after oral application. Department of Toxicology. Unpublished results. Study No. XIV/156. 14 Oct. 1966.

BASF AG (1984). Department of Product Safety. Laboratory of Ecology. Pruefbericht ueber eine Untersuchung auf biologische Abbaubarkeit im BSB5-Test - Cholinchlorid (German). Test No. 01606. 16 Feb. 1984.BASF AG (2004b). Department of Product Safety. Unpublished calculation. Mackay Level I V2.11. 29 Jun. 2004.

Bloom A., Galloway, S., Nakamura, F.T., Teteviri, A., Armstrong, M., Lavappa, K.L., Duk, S., and Ahmed, M.A. (1982). Comparison of results for SCE and chromosome aberrations for eleven compounds tested in two laboratories by standardized methods. Environ. Mutagen. 4: 397.

Boyd, W.D., Graham-White, J., Blackwood, G., Glen, I., and McQueen, J. (1977). Clinical effects of choline in Alzheimer senile dementia. Lancet 2: 711.

Colgate-Palmolive (2003). Study No. DCR-200-137-TKL. TKL Research Inc. Paramus, NJ, USA. In: SCCNFP. Scientific Committee on Cosmetic Products and Non-Food Products. Choline Chloride. SCCNFP/0672/03. 9 Dec. 2003.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Galloway, S.M., Bloom, A..D, Resnick, M., Margolin, B.H., Nakamura, F., Archer, P., and Zeiger, E, (1985). Development of a standard protocol for in vitro cytogenetic testing with Chinese hamster ovary cells: Comparison of results for 22 compounds in two laboratories. Environ. Mutagen. 7: 1-51.

Haworth, S., Lawlor, T., Mortelmans, K., Speck, W., and Zeiger, E. (1983). Salmonella mutagenicity test results for 250 chemicals. Environ. Mutagenesis Suppl. 1: 3-142.

Institute of Medicine [IOM] (2000). Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. . Standing Committee on the Scientific Evaluation of Dietary Reference Intake, Institute of Medicine, National Academy Press, Washington D.C.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Litton Bionetics (1977). Mutagenic evaluation of compound FDA75-69.000067-48-1. choline chloride. FCC. Report No. PB-266 891. Mar. 1977.

MITI (1992). Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan. Edited by Chemicals Inspection & Testing Institute Japan, published by Japan Chemical Industry Ecology-Toxicology & Information Center. October 1992.

MOE Japan (1999a). Ministry of Environment. Acute toxicity study of choline chloride on the Orange killifish *Oryzias latipes*. Unpublished study. No. 1998-16.

MOE Japan (1999b). Ministry of Environment. Acute toxicity study of choline chloride on *Daphnia magna*. Unpublished study. No. 1998-14.

MOE Japan (1999c). Ministry of Environment. Acute toxicity study of choline chloride on the freshwater alga *Pseudokirchnerialla subcapitata*. Unpublished study. No. 1998-13.

MOE Japan (1999d). Ministry of Environment. Chronic toxicity study of choline chloride on the freshwater invertebrate *Daphnia magna*. Unpublished study. No. 1998-15.

OECD (2004). SIDS Initial Assessment Report for Choline chloride (CAS No. 67-48-1), UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/67481.pdf

Shivapurkar, N., Hoover, K.L., and Poirier, L.A. (1986). Effect of methionine and choline on liver tumor promotion by phenobarbital and DDT in diethylnitrosamine-initiated rats. Carcinogenesis 7: 547- 550.

Tunkel J., Howard, P.H., Boethling, R.S., Sitteler, W., and Loonen, H. (2000). Predicting ready biodegradability in the Japanese Ministry of international trade and industry test. Environ. Toxicol. Chem. 19: 2478-2485.

U.S. Environmental Protection Agency [EPA] (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Zeisel, S.H., Story, D.C., Wurtman, R.J., and Brunengraber, H. (1980). Uptake of free choline by isolated perfused rat liver. Proc. Natl. Acad. Sci. USA 77(8): 4417-4419.

Zeisel, S.H., and Blusztajn, J.K. (1994). Choline and human nutrition. Ann. Rev. Nutr. 14: 269-296.

GUAR GUM

This dossier on guar gum (CAS RN 9000-30-0) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the chemistry database PubChem. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): disodium;[[[5-(6-aminopurin-9-yl)-3-hydroxyoxolan-2-yl]oxy-methoxyphosphoryl]oxy-oxidophosphoryl] hydrogen phosphate

CAS RN: 9000-30-0

Molecular weight: 535.15 g/mol; 200,000 to 300,000 daltons (Glickman, 1969)

Molecular formula: $C_{10}H_{14}N_5Na_2O_{12}P_3$

Synonyms: GU-052, guar flour, guaran, gum guar, slocose

SMILES:: COP(=O)(OC1C(CC(O1)N2C=NC3=C(N=CN=C32)N)O)OP(=O)([O-])OP(=O)(O)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Guar Gum

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Off-white to yellowish-white powder	-	PubChem
Vapour Pressure	Negligible	-	PubChem
Water Solubility	< 1 g/L @ 20°C (insoluble)	-	PubChem

III. ENVIRONMENTAL FATE PROPERTIES

Guar gum is a carbohydrate polymer consisting of D-mannose and D-galactose sugars from the guar plant or cluster bean. As a high molecular weight polysaccharide polymer, guar gum is expected to have a negligible vapour pressure. If released to air, a negligible vapour pressure indicates guar gum will exist solely in the particulate phase in the atmosphere. Particulate-phase guar gum will be removed from the atmosphere by wet and dry deposition. If released to soil, guar gum is expected to have no mobility since it is a polymer that binds strongly with soil particles. Volatilisation from moist soil surfaces is not expected to be an important fate process based upon a negligible Henry's Law constant. Likewise, guar gum is not expected to volatilise from dry soil surfaces based upon its vapour pressure. If released into water, guar gum is expected to adsorb to suspended solids and sediment (PubChem). Half-life data was not available.

Guar gum is expected to readily undergo microbial biodegradation in the environment (on the basis that it is a polysaccharide and expected to be readily biodegradable), and the potential to bioaccumulate in organisms is considered to be low (DoEE, 2017 and USEPA, 2005).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Guar gum exhibits very low acute toxicity by the oral route. It is non-irritating to the skin and minimally irritating to the eyes. Repeated dose toxicity studies in rats showed minimal toxicity from exposure to guar gum in the diet. Guar gum is not genotoxic or carcinogenic. Oral exposure to guar gum did not affect fertility in rats; nor was there any indication of developmental toxicity in either rats or mice.

NICNAS has assessed Guar Gum in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,060 mg/kg (Graham *et al.*, 1981) [Kl. Score = 2].

C. Irritation

Guar gum is non-irritating to the skin and minimally irritating to the eyes (McCarty *et al.*, 1990). Nonetheless, ECHA warns that the substance may cause serious eye irritation.

D. Sensitisation

There were reports of workers sensitised to guar gum in a carpet-manufacturing plant. Immediate skin reactivity to guar gum was observed in 8 out of 162 employees, and 11 of 133 participants had serum IgE antibodies to guar gum. These findings are difficult to interpret since carbohydrates, such as guar gum, are generally not associated with allergenicity (Malo, 1990).

E. Repeated Dose Toxicity

Oral

Male and female Osborne-Mendel rats were given diets containing 0, 1, 2, 4, 7.5, or 15% guar gum for 91 days. The average daily intakes are: 0; 580; 1,187; 2,375; 4,561 and 10,301 mg/kg/day for males; and 0; 691; 1,362; 2,762; 5,770 and 13,433 mg/kg/day for females. There were no deaths during the study. Body weights were significantly decreased in the ≥1% females and the ≥7.5% males; biologically significant changes (>10%) were seen in the 7.5% females and the 15% males. Liver weights were decreased in the ≥1% dietary groups. Kidney weights were decreased in the ≥7.5% dietary groups and were borderline significant in the 4% group. The 15% group males had reduced bone marrow cellularity; although the level was within normal limits, several of the rats were at the lower end of the normal range.

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9000-30-0%2C+

The NOAEL for this study is 4% in the diet or 2,762 mg/kg/day based on reduced body weights in the female rats (Graham *et al.*, 1981) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0; 6,300; 12,500; 25,000; 50,000 or 100,000 ppm guar gum for 13 weeks. Mean body weights were decreased in the 100,000 ppm male rats and in the ≥50,000 ppm female mice. A dose-related decrease in feed consumption was observed for male and female rats; male and female mice were comparable or higher than that of controls. There were no compound-related clinical signs or histopathological effects. The NOAELs for this study are 50,000 and 25,000 ppm for rats and mice, respectively. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs corresponds to 2,500 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks. Mean body weights of the high-dose females were lower than those of the controls after week 20 for mice and week 40 for rats. No compound-related clinical signs or adverse effects on survival were observed. Feed consumption by dosed rats and mice of either sex was lower than that of controls. There were no non-neoplastic histopathological effects in either rats or mice that were treatment-related. The NOAEL for both rats and mice is 25,000 ppm. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs correspond to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

Guar gum was not mutagenic to *S. typhimurium* strains TA 97, TA 98, TA 100, TA 102, TA 104, TA 1535, TA 1537, and TA1538 in the presence or absence of metabolic activation (Zeiger *et al.*, 1992) [Kl. Score = 2].

In Vivo Studies

Guar gum was inactive in a rat bone marrow cytogenetic assay at doses up to 5,000 mg/kg (Johnson *et al.*, 2015) Kl. Score = 4].

In a rat dominant lethal mutation test, rats were dosed by oral gavage with either a single or multiple doses of up to 5,000 mg/kg guar gum. There was no indication of a mutagenic effect by guar gum (Lee *et al.*, 1983) [Kl. Score = 2].

G. Carcinogenicity

Male and female F344 rats were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. There were increased incidences of

adenomas of the pituitary in male rats and pheochromocytomas of the adrenal medulla in female rats that were statistically significant, but these differences were considered to be unrelated to guar gum administration. When pituitary adenomas or carcinomas and when pheochromocytomas or malignant pheochromocytomas were combined, the statistical differences disappeared. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for F344 rats (NTP, 1982) [Kl. Score = 2].

Male and female $B6C3F_1$ mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. Hepatocellular carcinomas occurred in treated male mice at incidences that were significantly lower than that in controls. The combined incidence of male mice with either hepatocellular adenomas or carcinomas was also significantly lower in the high-dose group. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for $B6C3F_1$ mice (NTP, 1982) [Kl. Score = 2].

H. Reproductive Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intakes for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. Fertility was unaffected by treatment. There were slightly fewer corpora lutea and implantations in the 15% dietary group, but implantation efficiency was unaffected. The NOAEL for reproductive toxicity is 5,200 mg/kg/day (Collins *et al.*, 1987) [Kl. Score = 2].

I. Developmental Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intake for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. There were no deaths during the study. In the 15% group, the number of viable foetuses per litter were slightly reduced but was not statistically significantly different from controls. The authors indicated that the reduction may have been an effect of the decreased number of corpora lutea because the number of resorptions was unaffected in this treatment group. There was no treatment-related effect on foetal development or sex distribution, and there were no teratogenic effects (Collins *et al.*, 1987) [Kl. Score = 2].

Pregnant female rats were dosed by oral gavage with 0, 9, 42, 200 or 900 mg/kg guar gum on GD 6 to 15. There was no maternal or developmental toxicity at any dose level. The NOAEL for maternal and developmental toxicity is 900 mg/kg/day (FDRL, 1973) [Kl. Score = 2].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 8, 37, 170, or 800 mg/kg guar gum on GD 6 to 15. A significant number of deaths (6 out of 29) occurred in the 800 mg/kg dose group. There were indications of maternal toxicity in the surviving high-dose dams. There was no developmental toxicity at any dose level. The NOAELs for maternal and developmental toxicity are 170 and 800 mg/kg/day, respectively (FDRL, 1973) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for guar gum follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

In a two-year NTP chronic bioassay, female rats and mice given 50,000 ppm guar gum in their feed had lower body weights. There were no treatment-related non-neoplastic lesions in either rats or mice. The NOAEL for this study is 25,000 ppm for rats and mice, which corresponds to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice.

The NOAEL of 1,250 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 1,250/(10 x 10 x 1 x 1 x 1) = 1,250/100 = 13 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (13 x 70 x 0.1)/2 = 46 mg/L

B. Cancer

Guar gum was not carcinogenic to rats or mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Guar gum does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Guar gum is a polysaccharide polymer. It has low acute toxicity concern for fish but exhibits moderate acute toxicity to invertebrates (*Daphnia*).

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} for *Oncorhynchus mykiss* is 218 mg/L (Biesinger *et al.*, 1976) [Kl. Score = 2].

The 48-hour and 96-hour LC_{50} values for *Daphnia magna* are 42 mg/L and <6.2 mg/L, respectively (Biesinger *et al.*, 1976) [Kl. Score = 2].

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for guar gum follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. The acute LC_{50} values are available for fish (218 mg/L) and *Daphnia* (<6.2 mg/L). No chronic studies are available. On the basis that the data consists of acute studies from two trophic levels, an assessment factor of 1,000 has been applied to the lowest reported LC_{50} value of 6.2 mg/L for *Daphnia*. The $PNEC_{water}$ is 0.006 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{sediment}$ and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{soil}$ and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Guar gum is a naturally occurring polysaccharide from the guar plant or cluster bean; it expected to be readily biodegradable. Thus it is not expected to meet the screening criteria for persistence.

The potential to bioaccumulate in organisms is considered to be low. Thus guar gum is not expected to meet the criteria for bioaccumulation.

There are no adequate chronic aquatic toxicity studies available on guar gum. The acute LC_{50} values for guar gum are >1 mg/L in fish and invertebrates. Therefore, guar gum does not meet the screening criteria for toxicity.

The overall conclusion is that guar gum is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Aquatic Toxicity Category 2

B. Labelling

Warning!

According to the classification provided by companies to ECHA in CLP notifications, this substance causes serious eye irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Remove contaminated clothing. Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

Notes to Physician

May cause asthma-like (reactive airways) symptoms.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus for fire fighting.

C. Accidental Release Measures

Personal Precautions

Avoid dust formation.

Environmental Precautions

No special environmental precautions required.

Steps to be Taken if Material is Released or Spilled

Sweep up and dispose in suitable, closed containers.

D. Storage And Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard specifically for guar gum.

Engineering Controls

Ensure adequate ventilation.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Handle with gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Guar gum is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Biesinger, K.E., Lemke, A.E., Smith, W.E., and Tyo, R.M. (1976). Comparative toxicity of polyelectrolytes to selected aquatic animals. J. Water Pollut. Control Fed. 48: 183-187; cited in U.S. EPA ECOTOX database.

Collins, T.F.X., Welsh, J.J., Black, T.N., Graham, S.L., and O'Donnell, M.W., Jr. (1987). Study of the teratogenic potential of guar gum. Food Chem. Toxicol. 25: 807-814.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Food and Drug Research Laboratories, Inc. [FDRL]. (1973). Teratologic evaluation of FDA 71-16 (guar gum) in mice, rats, hamsters, and rabbits. Final report prepared under DHEW contract No. FDA 71-260. Maspeth, NY. NTIS No. PB-223-819/4; cited in CIR (2015).

Glickman M. (1969). Gum technology in the Food Industry, pp. 590, Academic Press, New York; cited in Yoon *et al.* (1998).

Graham, S.L., Arnold, A., Kasza, L., Ruffin, G.E., Jackson, R.C., Watkins, T.L., and Graham, C.H. (1981). Subchronic effects of guar gum in rats. Fd. Cosmet. Toxicol. 19: 287-290.

Johnson, W., Jr., Heldreth, B., Bergfeld, W.F., Belsito, D.V., Hill, R.A., Klaassen, C.D., Liebler, D.C., Marks, J.G., Jr., Shank, R.C., Slaga, T.J., Snyder, P.W., and Andersen, F.A. (2015). Safety assessment of galactomannans as used in cosmetics. Int. J. Toxicol. 34(Suppl. 1): 35S-65S.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lee, W.R., Abrahamson, S., Valencia, R., Von Halle, E.S., Wuergler, F.E., and Zimmering, S. (1983). The sex-linked recessive lethal test for mutagenesis in *Drosophila melanogaster*. A report of the U.S. Environmental Protection Agency Gene-Tox Program. Mutat. Res. 123: 183-279.

Malo, J.L., Cartier, A., L'Archevêque, J., Ghezzo, H., Soucy, F., Somers, J., and Dolovich, J. (1990). Prevalence of occupational asthma and immunologic sensitization to guar gum among employees at a carpet-manufacturing plant. J. Allergy Clin. Immunol. 86: 562-569.

McCarty, J.D., Weiner, M., Freeman, C., Aguinaldo, E.R., and Fletcher, M.J. (1990). Primary skin and ocular irritation studies on five food additive plant gums. J. Am. Coll. Toxicol. 1(1): 50-51.

NTP. (1982). NTP Technical Report on the Carcinogenesis Bioassay of Guar Gum (CAS No. 9000-30-0) in F344 Rats and B6C3F_1 Mice (Feed Study), National Toxicology Program, Research Triangle Park, NC.

PubChem. PubChem open chemistry database: https://pubchem.ncbi.nlm.nih.gov

United States Environmental Protection Agency [USEPA]. (2005). Science Assessment for Hydroxypropyl Guar Gum, Lower Risk Pesticide Chemical Focus Group, Office of Prevention, Pesticides and Toxic Substances, US Environmental Protection Agency. Accessed: http://www.epa.gov/opprd001/inerts/hydroxypropyl.pdf

Zeiger, E., Anderson, B., Haworth, S., Lawlor, T., and Mortelmans, K. (1992). Salmonella mutagenicity tests: V. Results from the testing of 311 chemicals. Environ. Mol. Mutagen. 21: 2-141.

ULEXITE

This dossier on ulexite presents the most critical studies pertinent to the risk assessment of ulexite in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium-calcium pentaborate octahydrate

CAS RN: 1319-33-1

Molecular formula: $(NaCaB_5O_6(OH)_6 \bullet 5H_2O)$

Molecular weight: 405 g/mol

Synonyms: Ulexite; sodium-calcium pentaborate octahydrate

Smiles: B1(OB2OB(O1)OB(O2)OB([O-])[O-])[O-].O.O.O.O.O.O.O.O.[Na+].[Ca+2]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Commercially Available Ulexite

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, granular, ground or powder form	4	Etimine USA, Inc. (2016)
Melting Point	870°C	4	Etimine USA, Inc. (2016)
Boiling Point	Not Applicable	-	-
Bulk Density	1,410 to 1,500 kg/m^3	4	Etimine USA, Inc. (2016)
Water solubility	26.67% as dissolved Ulexite @ 25°C by weight of solution	4	American Borate Company (2016)

Ulexite is a naturally-occurring mineral that is slightly soluble in water. Limited measured data are available for ulexite. In a study investigating the relative rates of boron from soluble and controlled-release boron fertilizers, ulexite showed releases of boron of 20% in just under 10 weeks; 40% in approximately 25 weeks; 60% by 40 weeks; and 80% by 60 weeks (Broschat, 2008). In the environment, borates will dissociate and/or hydrolyse to release boron as boric acid [$B(OH)_3$ (also formulated as H_3BO_3)] and/or borate anions. Therefore, the information presented within this dossier is for boron (CAS No. 7440-42-8).

III. ENVIRONMENTAL FATE PROPERTIES

Boron is found almost exclusively in the environment in the form of boron-oxygen compounds, which are often referred to as borates. In the environment, borates and compounds of boric acid will dissociate and/or hydrolyse to form the same boron species. For example, when borax dissolves in dilute solutions, it dissociates into Na+ ions and the tetraborate anion ($B_4O_5(OH)_4^{2-}$). Boric acid ($B(OH)_3$) is formed following acid catalysed hydrolysis of the tetraborate anion. Under alkaline conditions, dilute solutions of the tetraborate anion depolymerise rapidly to the mononuclear borate anion ($B(OH)_4^-$) (DoEE, 2017).

Boron is an inorganic, elemental compound and can therefore not be biodegraded by micro-organisms or other biotic-related processes (ECHA).

The WHO (1998) review of boron noted that highly water-soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated (ECHA).

Bioconcentration factors of < 0.1 to 10.5 L/kg have been reported from laboratory tests of fish and oysters (Thompson et al. 1976). Saiki et al. (1993) measured boron levels in aquatic food chains and observed the highest concentrations of boron in detritus and filamentous algae. Invertebrates and fish had lower concentrations, indicating that bioaccumulation was not occurring. Based on these data, boron does not bioaccumulate in the aquatic environment (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

No information is available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No values were derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ulexite does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no mammalian or aquatic toxicity studies on ulexite. Toxicity for boron is provided within this section.

Boron is of a low toxicity concern to aquatic organisms. Although boron is required by plants at low concentrations, at high concentrations it is toxic. In Australia, it is generally accepted that boron toxicity will pose a risk to terrestrial plants when soil concentrations exceed 15 mg/kg of extractable boron. The phytotoxicity of boron is dependent on the plant species and soil type (DoEE, 2017).

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies on boron.

Table 2: Acute Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
P. promelas	4-day LC_{50}	79.7 mg/B/L	2	ECHA
Freshwater invertebrates	48-hr LC_{50}	64 to >544 mg/B/L	2	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	52.4 mg/B/L	2	ECHA

1 – CAS No. 7440-42-8

Chronic Studies

Table 3 lists the results of chronic aquatic toxicity studies on boron.

Table 3: Chronic Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Micropterus salmoides	4d-EC_{10}	36.8 mg/B/L	2	ECHA
Oncorhynchus mykiss	long term NOEC-LOEC	19.2. mg/B/L	2	ECHA
Brachydanio rerio	long term NOEC-LOEC	36.mg/B/L	2	ECHA
Pimephales promelas	long term NOEC-LOEC	21.3 mg/B/L	2	ECHA
Daphnia magna	NOEC	13.9 mg/B/L	2	ECHA
Hyalella Azteca	NOEC	6.3 mg/B/L	2	ECHA
Chironomus riparius	NOEC	20.1 mg/B/L	2	ECHA
Brachionus calyciflorus	NOEC	24.6 mg/B/L	2	ECHA
Lampsilis siliquoidea	NOEC	30 mg/B/L	2	ECHA

1 – CAS No. 7440-42- 8 for boron

ANZG has developed a water quality guideline for boron (ANZG, 2021). Very high reliability default guideline values (DGVs) for (dissolved) boron in freshwater were derived from 22 chronic (long-term) toxicity data, comprising eight fish, two amphibians, three crustaceans,

one bivalve, three macrophytes, one green microalga, three diatoms and one blue–green alga. The DGVs for 99, 95, 90 and 80% species protection are 340 µg/L, 940 µg/L, 1,500 µg/L and 2,500 µg/L, respectively. The 95% species protection level for boron in freshwater (940 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems.

C. Terrestrial Toxicity

Relevant and reliable chronic no-effects values were identified for 39 terrestrial species or microbial processes. No-effect levels for dissolved boron ranged between 7.2 mg B/kg soil dw and 86.7 mg B/kg soil dw. The plant *Zea mays* was the most sensitive trophic level. The least sensitive species was the nematode *C.elegans*. A Species Sensitivity Distribution (SSD) has been developed for the assessment of boron in the terrestrial compartment, using the reliable species-specific chronic toxicity effect levels that have been generated in various research studies (ECHA) [KI Score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ulexite is a naturally-occurring mineral. For the purposes of this PBT assessment, the persistence criteria is not considered applicable to this inorganic substance.

Bioaccumulation is not applicable to naturally-occurring minerals, such as ulexite. Although boron is slowly released from ulexite, limited data indicate that bioaccumulation is not significant in aquatic and terrestrial food chains. Thus, it does not meet the criteria for bioaccumulation.

There are no aquatic toxicity studies on ulexite. The lowest chronic toxicity value for boron is > 0.1 mg/L. The acute E(L)C_{50} values for boron is > 1 mg/L. Thus, based on boron, ulexite does not meet the criteria for toxicity.

Therefore, ulexite is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

GHS07, GHS08

B. Labelling

Warning!

Danger!

According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child and causes serious eye irritation.

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Ulexite is non-flammable, combustible, or explosive. It is a flame retardant.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Ulexite is slightly water-soluble; at high concentrations it may cause damage to trees or vegetation by root absorption. Do not flush to drains.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ulexite.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Ulexite is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

American Borate Company. (2016). Technical specifications on Ulexite 45 micron ground. Available at: http://www.americanborate.com/media/19191/ulexite-1319-33-1-2016-technical-specification.pdf.

ANZG. (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Broschat, T.K. (2008). Release rates of soluble and controlled-release boron fertilizers. HorTechnology 18(3): 471-474.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Etimine USA, Inc. (2016). Safety Data Sheet on Ulexite. Available at: http://www.etimineusa.com/sites/etimineusa.com/files/SDS%20-%20Ulexite%202016%20-%202018_0.pdf

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Saiki, M.J., Jennings, M.R., and Brumbaugh, W.B. (1993). Boron, Molybdenum, and Selenium in aquatic food chains from the Lower San Joaquin River and its tributaries, California. Archives of Environmental Contamination and Toxiciology. 24, 307-319.

Thompson et al. (1976). Toxicity, uptake and survey studies of boron in the marine environment. Water Research Vol. 10. pp 869 to 875, 1976.

WHO. (1998). World Health Organisation, Environmental health criteria 204 – boron, viewed 26 August 2015. http://www.inchem.org/documents/ehc/ehc/ehc204.htm.

ETHYLENE GLYCOL

This dossier on ethylene glycol presents the most critical studies pertinent to the risk assessment of ethylene glycol in its use in hydraulic fracturing fluids. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ethane-1,2-diol

CAS RN: 107-21-1

Molecular formula: $C_2H_6O_2$ ($HOCH_2CH_2OH$)

Molecular weight: 62.07 g/mol

Synonyms: Ethylene glycol; ethane-1,2-diol; 1,2-ethanediol, 2-hydroxyethanol; monoethylene glycol; MEG; glycol alcohol; EG

SMILES: C(CO)O

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Ethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20oC and 101.3 kPa	Colourless and odourless syrupy liquid	2	ECHA
Melting Point	-13°C @ 101.3 kPa	2	ECHA
Boiling Point	197.4°C @ 101.3 kPa	2	ECHA
Density	1110 kg/m3@ 20°C	2	ECHA
Vapour Pressure	12.3 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-1.36 (calculated) @ 25°C	2	ECHA
Water Solubility	1000 g/L @ 20°C	2	ECHA
Flash Point	111°C	2	ECHA
Auto flammability	398°C	2	ECHA
Viscosity	16.1 mPa s @ 25°C	2	ECHA
Henry's Law Constant	0.133 @ 25°C (QSAR)	2	ECHA

III. ENVIRONMENTAL FATE SUMMARY

A. Summary

Ethylene glycol is readily biodegradable, and it is not expected to bioaccumulate. Ethylene glycol has low potential to adsorb to soil and sediment.

B. Biodegradation

Ethylene glycol was readily biodegradable in an OECD 301A test. After 10 days, degradation was 90-100% (ECHA) [Kl. score = 1]. There was 97% degradation after 20 days in a BOD test; and 96% degradation after 28 days in an OECD 301D test (Waggy et al., 1994; OECD, 2004a,b) [Kl. score = 2]. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

The aerobic degradation of ethylene glycol was measured from grab river water samples at 4, 8 and 20°C. At 20°C, ethylene glycol was completely degraded in three days in all river waters tested; at 8°C, degradation was complete within 14 days. Degradation at 4°C was substantially slower, with degradation of < 20% after 14 days in river samples with limited suspended matter and a starting concentration of 10 mg/L (Evans and David, 1974).

C. Environmental Distribution

No experimental data are available for ethylene glycol. Using KOCWIN in EPISuite™ (USEPA, 2017), the estimated K_{oc} values from the molecular connectivity index (MCI) and from the log K_{ow} are 1 and 0.2239 L/kg, respectively.

Based upon these K_{oc} values, if released to soil, ethylene glycol is expected to have low potential for adsorption and a high potential for mobility. If released to water, based on its K_{oc} and high water solubility values, ethylene glycol is likely to remain in water and not adsorb to sediment. From the water surface, the substance will not evaporate into the atmosphere (ECHA).

D. Bioaccumulation

The calculated log K_{ow} for ethylene glycol is -1.36 (ECHA). The BCF for ethylene glycol in golden ide (*Leuciscus idus melanotus*) after three days of exposure was determined to be 10 (Freitag *et al.*, 1985). Bioaccumulation is not to be expected.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity. The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg. Ethylene glycol is not a skin irritant or a skin sensitiser in laboratory animals. In humans, ethylene glycol may cause skin irritation; there is also a low potential for skin sensitisation. It is not an eye irritant. The kidney is the primary target organ from repeated exposures. The proposed mode-of-action (MOA) for the kidney damage involves the formation of a precipitate or crystals from the ethylene glycol metabolite oxalic acid with calcium in the urine. Ethylene glycol is not genotoxic or carcinogenic to rodents. Ethylene glycol did not affect fertility in animal studies, but it did cause developmental effects. In rodents, the

developmental effects caused by oral doses of ethylene glycol include teratogenic effects (craniofacial and axial-skeletal malformations and variations). In contrast, no developmental toxicity was seen in rabbit studies. The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits. Based on a physiologically-based pharmacokinetic (PBPK) model for ethylene glycol, humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity.

B. Metabolism

Ethylene glycol is almost completely absorbed in laboratory animals by the oral route (OECD, 2004a; Frantz et al., 1996a). A range of 1-51% of ethylene glycol is absorbed by the dermal route based on *in vivo* studies in rodents (Frantz et al., 1996a,b).

The main metabolic pathway for metabolism of ethylene glycol is oxidation via alcohol dehydrogenases and aldehyde dehydrogenases. The main metabolites of ethylene glycol are carbon dioxide, oxalic acid and glycolic acid (OECD, 2004a).

The relevant metabolite for the repeated dose toxicity studies is oxalic acid, which is slowly transported from the liver to the kidneys, where is forms calcium-oxalate crystals (Corley et al., 2005a).

The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits (Carney et al., 1998).

A physiologically-based pharmacokinetic (PBPK) model has been developed for ethylene glycol. When internal dose surrogates were compared in rats and humans over a wide range of exposures, it has been concluded that humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity (Corley et al., 2005b).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,712 mg/kg (ECHA) [Kl. score = 2]. The 6-hour inhalation LC_{50} value for male and female rats was > 2.5 mg/L (Tyl et al., 1995a) [Kl. score = 2]. The dermal LD_{50} for male and female mice is > 3,500 mg/kg (Tyl et al., 1995b) [Kl. score = 2].

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity (ECHA). The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg (Hess et al., 2004).

D. Irritation

Application of 0.5 mL of ethylene glycol to the skin of rabbits for 23 hours under occlusive conditions was not irritating (Guillot et al., 1982) [Kl. score = 2].

In a Human Repeated Insult Patch Test (HRIPT), ethylene glycol was applied to the skin for 24 hours under occlusive or semi-occlusive conditions for nine times during the induction phase. The induction phase was followed by a rest period of two weeks, followed by a 24-hour challenge on the sixth week of the study. Erythema was seen in a small proportion of the 401 subjects that completed the study. Under the conditions of the study, three subjects had reactions on challenge that were

indicative of possible irritation and/or low-level sensitisation. These three subjects were re-challenged under occlusive or semi-occlusive conditions one or two weeks later. Re-challenge testing was negative for one subject, but the other two subjects were judged to have irritant reactions to ethylene glycol since their reactions were similar or lesser compared to the skin responses observed during the induction period, and the skin reactions were not greater over time after the challenge or re-challenge (ECHA).

Instillation of 0.05 mL of ethylene glycol into the eyes of rabbits was not irritating (ECHA) [Kl. score = 2].

E. Sensitisation

Ethylene glycol was not a skin sensitiser to guinea pigs in a Magnusson and Kligman test (Kurihara et al., 1996) [Kl. score = 2]. In a HRIPT, ethylene glycol was considered to have a low potential for dermal sensitisation in humans (ECHA).

F. Repeated Dose Toxicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5% ethylene glycol for 13 weeks. Mortality was seen in the 5% males, but not in females. Mean weight gain was significantly decreased in the 2.5 and 5% males; there was no significant differences in female rats. Feed consumption was similar across all groups. A significant increase was seen in the left kidney weight in the 2.5 and 5% dose groups (both sexes); this was not seen in the right kidneys. Mean thymus ratio to terminal body weight was significantly decreased in the 5% males. Serum urea nitrogen levels were significantly increased in the 2.5 and 5% males, and significantly increased in the ≥ 0.32% females. Creatinine levels were decreased in the 0.32% groups and significantly increased in the 2.5 and 5% groups. The 2.5% and 5% male rats had kidneys that were rough, granular and/or pitted appearances. The 5% females showed nephrosis, and the 5% males had clusters of crystals in the brain. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2]

Male and female Sprague Dawley rats were given in their drinking water ethylene glycol for 90 days. The concentrations for females were 0, 0.5, 1.0, 2.0 or 4.0% (0, 597, 1,145, 3,087 or 5,744 mg/kg/day). The concentrations for males were 0, 0.25, 0.5, 1.0 or 2.0% (0, 205, 407, 947 or 3,134 mg/kg/day). In the 4% groups, there was mortality and decreased body weights (males only). Significant organ weights were noted only in males. Kidney weights were significantly increased in the 1% and 2% males; heart, liver and lung were significantly decreased in the 2% males. The 4% males also had a significant increase in the brain and gonads relative to body weights. Leukocyte levels were significantly decreased in the 0.5, 2 and 4% females, but not in males. Significant differences were noted in LDH, creatinine, ALT, calcium and glucose in the 1% males; and phosphorus, BUN and creatinine in the 2% males. There were significant increases in phosphorus in the 1% females and glucose in the 0.5 and 4% females. Kidney lesions were seen in the ≥ 2% females and in the ≥ 1% males, with the lesions more prominent in males than in females. The kidney changes consisted of tubular dilation, tubular degeneration, acute inflammation, birefringent crystals in tubules and pelvic epithelium. The NOAEL for this study is 407 mg/kg/day for males. The LOAEL for females is 597 mg/kg/day; a NOAEL was not established (Robinson et al., 1990) [Kl. score = 2]

Male and female B6C3F$_1$ mice were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5.0% ethylene glycol for 13 weeks. There was no mortality and no treatment-related effect on mean weight gain and feed consumption. Organ/body weight ratios were similar across all groups. Serum urea nitrogen and creatinine levels were unaffected. Kidney effects were seen in the male, but not female, mice. Kidney lesions were observed in half of the 5% male mice and one mouse in the 2.5% dose level. Lesions were tubular dilation, cytoplasmic vacuolisation and regenerative hyperplasia of tubular cells. There was no evidence of crystal formation in the tubules. These changes were focal, randomly distributed and of minimal to mild severity. Hyaline degenerative of the liver was present in the centrilobular hepatocytes in all of the 2.5% and 5% males. These cells showed cytoplasmic accumulations of non bifringent, eosinophilic (hyaline), globular or crystalline material which resembled erythrocytes in size, shape and tinctorial properties. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2].

Male Fischer 344 and Wistar rats were given in their feed 0, 150, 500 or 1,000 mg/kg ethylene glycol for 16 weeks. At 1000 mg/kg, the following effects were seen: mortality in Wistar strain (2/10) with prior clinical observations of emaciation and dermal atonia and macroscopic findings of changes in kidneys (pale, calculi) and small seminal vesicles in these animals; mean body weight losses, lower mean body weights and mean cumulative body weight changes in Wistar strain (weeks 2 – 16); lower mean food consumption in Wistar strain; higher mean water consumption in both F344 and Wistar strains; lower mean specific gravity and higher mean total urine volume in both F344 and Wistar strains; macroscopic findings of pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weights in both F344 and Wistar strains; renal macroscopic findings of crystal nephropathy in Wistar and F-344 rats, with more severe nephropathy in Wistar strain than in the F344 strain. At 500 mg/kg, the following effects were seen: lower mean body weights (study weeks 3, 6-8 and 10-12) and mean cumulative body weight changes in the Wistar strain throughout the study with slightly lower mean food consumption throughout the study; higher mean water consumption in the Wistar strain; lower mean urine specific gravity and higher mean total urine volume in the Wistar strain; macroscopic findings in the Wistar strain consisting of predominantly pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weight in the Wistar strain; renal macroscopic findings of crystal nephropathy in Wistar and F-344 strains, with more severe nephropathy in the Wistar strain than in the F344 strain. The NOAEL in both the F344 and Wistar rats is 150 mg/kg/day (Cruzan et al., 2004) [Kl. score = 2].

Male Wistar rats were given in their feed 0, 50, 150, 300 or 400 mg/kg ethylene glycol for 12 months. There was mortality in the 300 and 400 mg/kg dose groups (5/20 and 4/20, respectively); the remaining 400 mg/kg animals were euthanised early (Day 203) due to excessive weight loss. The 300 mg/kg animals had increased water consumption and urine volume with decreased specific gravity, most likely due to osmotic diuresis. Calculi (calcium oxalate crystals) were found in the bladder and kidney pelvis in the ≥ 300 mg/kg animals. The ≥ 300 mg/kg rats that died prematurely had transitional cell hyperplasia with inflammation and haemorrhage of the bladder wall. Crystal nephropathy (basophilic foci, tubule or pelvic dilatation, birefringent crystals in the pelvic fornix, or transitional cell hyperplasia) was seen in all of the 400 mg/kg and most of the 300 mg/kg rats. These effects were not seen in the 50 or 150 mg/kg rats. Kidney oxalate levels, the metabolite responsible for the kidney toxicity, was not increased in the 50 and 150 mg/kg animals compared to the controls. The NOAEL for this study is 150 mg/kg/day (Corley et al., 2005) [Kl. score = 1].

Male and female Sprague-Dawley rats were given in their feed 0, 0.1, 0.2, 0.5, 1.0 or 4.0% ethylene glycol for two years. There was significant reduction in growth in the 4% males after week 16, and in the 1% males after week 70. The 4% females did not gain any weight past the first year of the study. Water consumption was double that of the controls in the 4% males that initiated soon after the

start of the study. The 1% males had significant increases in water consumption after 6 months and some increase was observed in the 0.5% males. Females only showed increased water consumption in the 4% group. There was 100% mortality in the 1 and 4% males, while mortality of additional dose levels were below that of the controls. There was 100% mortality in the 4% females, while the 1% females were similar to the controls; the 0.1, 0.2 and 0.5% females were increased compared to the controls. Since the 1 and 4% males and the 4% females all died before the study termination date, there are no data for these groups on terminal organ weight. For males, the terminal organ weights were decreased in all dose levels compared to the controls. For females, the organ weights were similar to the controls. The 1 and 4% males and females had kidneys with stones and crystals. The NOAEL for this study is 0.2% (data was insufficient to calculate the dose) (Blood, 1965) [Kl. score = 2].

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There were numerous adverse effects in the 1,000 mg/kg males and, to a lesser degree, in the 1,000 mg/kg females. The most remarkable effect was the production of urinary calculi in the kidneys, ureters and urinary bladders of the 1,000 mg/kg males, along with the presence of high levels of calcium oxalate in the urine. Increased incidences of tubular cell hyperplasia, tubular dilation, peritubular nephritis and focal granulomatous nephritis occurred in the 1,000 mg/kg males. Other significant findings in these males were markedly lower body weight gain, increased absolute and relative kidney weights, decreased absolute and relative liver weights, various hematopoietic changes and increased water consumption (likely a result of impaired kidney function). Histopathological changes in the 1,000 mg/kg males were mineralisation of the heart, lungs, stomach and vas deferens being the most noteworthy. The various adverse effects in these males resulted in reduced survival; there was increased mortality which became apparent by 8 months, with all males in this group died by month 16. Although calcium oxalate crystals were found in the urine of the 1,000 mg/kg females, no urinary calculi were seen. Absolute and relative kidney weights were increased in these rats. The most significant histopathologic finding in the 1,000 mg/kg females was fatty metamorphosis of the liver. There were transient changes in organ weights, erythroid parameters, water consumption rates and urine specific gravity in the 200 and 40 mg/kg rats; these effects were considered to be statistical artifacts attributable to chance. Focal soft mineralisation was observed in certain organs of the 200 and 40 mg/kg rats, which were considered to be the result of altered calcium metabolism associated with ingestion of ethylene glycol. The NOAEL for this study is considered to be 200 mg/kg/day (DePass et al., 1986a; ECHA) [Kl. score = 2].

Male and female B6C3F_1 mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) for 103 weeks. These concentrations are approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Survival, mean body weights and feed consumption was similar across all groups. There were no treatment-related clinical signs of toxicity. Liver lesions (males only) and arterial hyperplasia (females only) were observed at 12,500 ppm, but no adverse effects were observed at 6,250 ppm. The NOAEL for this study is 6,250 ppm in males, which corresponds to 1,500 mg/kg/day (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies in rodents or rabbits are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on ethylene glycol are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Ethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	+/-	-	2	McGregor et al. (1991)
Chromosomal aberration (CHO cells)	-	-	2	ECHA

*+, positive; -, negative

In Vivo Studies

A dominant lethal study was conducted in F344 rats given 0, 40, 200 or 1,000 mg/kg/day ethylene glycol in feed. There were slight increases in the dominant lethal mutation index in the high-dose and low-dose groups; these appear to be random occurrences and were not considered to be treatment-related. It was concluded that ethylene glycol was not genotoxic in this study (DePass et al., 1986b) [Kl. score = 2].

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There was increased mortality in the 1,000 mg/kg males, starting at 8 months and resulting in all males in this group dead by 16 months. Survival for the 1,000 mg/kg females and the 200 and 40 mg/kg males and females were similar to the controls. The incidence of mononuclear cell leukemia was statistically significantly higher in the 200 mg/kg males compared to the male controls, but not when compared to the pooled controls (males and females). Evaluation of the data by the method of Thomas et al. (2007), however, showed no treatment-related effect. It was concluded that ethylene glycol was not carcinogenic to rats in this study (DePass et al., 1986) [Kl. score = 2].

Male and female $B6C3F_1$ mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) ethylene glycol. These concentrations were approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Body weights, survival and incidence of tumours were similar between treated and control mice (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

I. Reproductive Toxicity

Ethylene glycol was assessed in a Reproductive Assessment by Continuous Breeding (RACB) protocol (Chapin and Sloane, 1997). The parental mice were administered ethylene glycol via drinking water during pre-mating exposure, cohabitation, pregnancy and lactation. The F_1 generation received prenatal exposure via maternal exposure during gestation, with the exposure continuing during lactation, weaning and mating of F_1 animals and production of an F_2 litter. The doses were 0, 0.25, 0.5 or 1% ethylene glycol, which corresponded to approximately 0, 410, 840 or 1,640 mg/kg/day. No adverse effects were noted in the parental animals at doses up to 1%. There was a small, but statistically significant, effects on the numbers of litters per fertile pair, the number of live pups per litter, and live pup weight in the 1% dose group. Neither the 0.25 nor 0.5% dose groups were significantly affected. The number of live pups per litter was lower in the treated groups, but differences were not statistically significant. Unusual facial features (i.e., shorter snout and wide-set eye) and skeletal defects (shortened frontal, nasal and parietal bones; fused ribs abnormally shaped or missing sternebrae, abnormally shaped vertebrae; and twisting of the spine) were noted on some of the offspring of the treated mice in the 1% group, but not in the controls. The parental NOAEL is 1% (approximately 1,640 mg/kg/day), and the NOAEL for reproductive toxicity is 0.5% (approximately 840 mg/kg/day (Lamb et al., 1985) [Kl. score = 2].

In a three-generation reproductive toxicity study, Fischer 344 rats were given in their diet 0, 40, 200 or 1,000 mg/kg/day ethylene glycol. There were no treatment-related effects on clinical signs of toxicity or survival in the parental animals. There were no significant effects on fertility index, gestation index, gestation survival for all three generations. Mean pup weights for each of the hree generations were similar between treated and control animals. The NOAEL for parental and reproductive toxicity is 1,000 mg/kg/day (DePass et al., 1986b) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Sprague-Dawley rats were dosed by oral gavage with 0, 50, 150, 500, 1,000 or 2,500 mg/kg ethylene glycol during gestational days (GD) 6-15. Maternal toxicity was observed in the 2,500 mg/kg group and consisted of significantly decreased body weights, increased water consumption, decreased uterine weights, increased kidney weights and increased relative liver weights. At 500 mg/kg, there were developmental effects, which included reduced foetal body weights, extra or missing ribs, missing arches and poor ossification in thoracic and lumbar centra. In the 2,500 mg/kg group, in addition to skeletal malformations, there was gastroschisis, hydrocephaly, lateral ventricle dilated (tissue depressed), umbilical hernia and atelectasis. The NOAELs for maternal and developmental toxicity are 1,000 and 500 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD rats were dosed by oral gavage with 0, 1,250 2,500 or 5,000 mg/kg ethylene glycol during GD 6-15. In the ≥ 2,500 mg/kg groups, the dams had increased relative kidney weights, decreased gravid uterine weight and increased water consumption. Maternal body weight gain was significantly decreased in the 1,250 mg/kg group. Live litter size was significantly decreased in the 5,000 mg/kg group and foetal body weights were decreased in the 1,250 and 5,000 mg/kg groups. Litters with malformed foetuses were observed in the ≥ 1,250 mg/kg groups. The LOAELs for maternal and developmental toxicity are 1,250 mg/kg/day; NOAELs were not established (Price et al., 1985) [Kl. score = 2].

Pregnant Fischer 344 rats were given by oral gavage 0, 40, 200 or 1,000 mg/kg ethylene glycol during GD 6-15. No maternal toxicity was observed at any dose level. There were no significant effects on preimplantation loss, foetal length, foetal weight, total implantations or litter size. There was an increased incidence of skeletal alterations in the 1,000 mg/kg group, which consisted of poorly ossified and unossified vertebral centra. No significant increases in the incidence of major malformations were observed. The NOAELs for maternal and developmental toxicity are 1,000 and 400 mg/kg/day (Maronpot et al., 1983) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 50, 150, 500 or 1,500 mg/kg ethylene glycol during gestational days (GD) 6 to 15. There was no maternal toxicity. At 1,500 mg/kg, there were reduced foetal body weights, fused ribs and arches, poor ossification in thoracic and lumbar centra and increased occurrence of an extra 14th rib. At 500 mg/kg, there was slight reductions in foetal body weight and increased incidences of extra ribs. The NOAELs for maternal and developmental toxicity were 1,500 and 150 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 750, 1,500 or 3,000 mg/kg ethylene glycol during GD 6 to 15. There was a significant decrease in maternal gain, gravid uterine weights and liver weights in the 1,500 mg/kg group. A decreased number of implantation sites per litter was observed in the 1,500 mg/kg group. Significant decrease in liver litter size was observed in the 3,000 mg/kg group and decreased foetal body weights were seen at ≥ 750 mg/kg. Litters with a significant increase in malformed foetuses were observed in the ≥ 750 mg/kg groups. There was a significant dose-related increase in post-implantation loss per litter, though there were no significant pairwise comparisons. The NOAEL for maternal toxicity is 750 mg/kg/day. The LOAEL for developmental toxicity is 750 mg/kg/day; the NOAEL was not established (Price et al., 1985) [Kl. score = 2].

In a short-term reproductive and developmental toxicity screen test, male and female Swiss Crl:CD-1 mice were allowed to mate over a three-day period. The males were dosed by oral gavage from study Day 3 to study Day 20. The Group A females were exposed throughout the 21-day test period; the Group B females were exposed during GD 8-14. The doses were 0, 250, 700 or 2,500 mg/kg ethylene glycol. The Group A females were sacrificed after 19 days of treatment, and the Group B females were allowed to litter and rear to postnatal day (PND) 4. There was no maternal or paternal toxicity. The 2,500 mg/kg females in Group A had significantly fewer liver implants and more dead implants. The 2,500 mg/kg in Group B had significantly lower total litter weights on PND 1 and 4. The NOAELs for parental and developmental toxicity are 2,500 and 700 mg/kg/day (Harris et al., 1992) [Kl. score = 2].

In a Chernoff/Kavlock assay, pregnant CD-1 mice were dosed by oral gavage with 0 or 11,090 mg/kg ethylene glycol during GD 7-14. The females were allowed to litter and rear to PND 3. Ten percent of the maternal animals died. The number of surviving pups per litter (40% survived), birth weight and pup weight gain were reduced. The LOAELs for maternal and developmental toxicity are 11,090 mg/kg; NOAELs were not established (Schuler et al., 1984; Hardin et al., 1987) [Kl. score = 2].

Pregnant female New Zealand White rabbits were dosed by oral gavage with 0, 100, 500, 1,000 or 2,000 mg/kg ethylene glycol on GD 6 to 19. At 2,000 mg/kg, eight of the 17 does (42.1%) died. Maternal body weights and body weight gain were similar across all groups. There was no developmental toxicity. The NOAEL for maternal toxicity is 1,000 mg/kg/day. The NOAEL for developmental toxicity is 2,000 mg/kg/day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female CD rats were dosed by oral gavage with 0, 250, 1,250 or 2,250 mg/kg ethylene glycol on GD 6 to 20. At 2,250 mg/kg, maternal body weight, body weight gain, kidney weight and postpartum uterine weight were significantly reduced. At 1,250 mg/kg, the gestational period was

lengthened and maternal kidney histopathological effects were noted. Developmental toxicity was noted in the 2,250 mg/kg group and included reduced pup weight, reduced viability and increased malformations (primarily hydrocephaly and abnormalities of the axial skeleton). No developmental toxicity was seen in the 1,250 mg/kg group. The NOAEL for maternal and developmental toxicity is 250 mg/kg/day (ECHA) [Kl. score = 2].

Inhalation

Pregnant female CD rats were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. There was no treatment-related mortality; a dose-related increased in clinical signs (red fur discoloration on the head and neck) was noted, which was considered to be a non-specific indication of stress. Body weights and body weight gain were unaffected by treatment. There was some evidence of treatment-related reductions in ossification of the foetal skeleton at 1,000 and 2,500 mg/m^3 (considered as fetotoxicity). The NOAECs from inhalation exposure cannot be determined due to confounding oral exposure during whole-body exposure. However, there was no maternal or embryotoxicity at 150 mg/m^3 and no teratogenicity at any aerosol concentration tested (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. Reduced maternal body weight was observed in the 2,500 mg/m^3 group on GD 12,15 and 18 and in the 1,000 mg/m^3 group on GD 18. Reduced maternal weight gain was also seen during GD 6-12, 6-15 and GD 6-18 for the ≥ 1000 mg/m^3 groups and for GD 5-18 for the 2,500 mg/m^3 group. Terminal body weights were reduced in the ≥ 1,000 mg/m^3 groups. Gravid uterine weight was also reduced in the ≥ 1,000 mg/m^3 groups, so that body weight corrected for gravid uterine weight was unaffected. The number of viable implantations per litter was reduced at 2,500 mg/m^3. The number of non-viable implantations per litter was elevated at ≥ 1,000 mg/m^3 because of a significant increase in late resorptions at 1,000 mg/m^3, and a significant increase in late resorptions and in dead foetuses at 2,500 mg/m^3. The number of early resorptions at 2,500 mg/m^3 was also elevated but not statistically. foetal body weights per litter (male, female and total) were reduced at ≥ 1,000 mg/m^3. There was a significant increase in the incidence of a number of external, visceral and skeletal malformation, as well as skeletal variations, at ≥ 1,000 mg/m^3. There was no observable maternal or developmental toxicity at 150 mg/m^3. However, a NOAEC cannot be determined because of the amount of ethylene glycol that may have been ingested from the presence of ethylene glycol on the fur (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (nose-only) to 0, 500, 1,000 or 2,500 mg/m^3. The study also included a group exposed to 2,100 mg/m^3 (not discussed here). Reduced maternal body weight gain were seen in the 2,500 mg/m^3 for GD 9-12, 12-15, 6-15 and 0-18. Absolute kidney weights were increased in the ≥ 1,000 mg/m^3 groups. foetal body weights per litter were significantly reduced for the 2,500 mg/m^3. In the 2,500 mg/m^3, there was a significant increase in one skeletal malformation (fusion of the ribs) and an increased incidence of skeletal variations. No other teratogenic effects were observed. The NOECs for maternal and developmental toxicity are 500 and 1,000 mg/m^3, respectively (Tyl et al., 1995c) [Kl. score = 2].

Dermal

Pregnant CD-1 mice were administered by dermal applications of 0, 400, 1,677 or 3,549 mg/kg ethylene glycol 6 hours/day on GD 6-15. There was minimal, if any, treatment-related maternal toxicity. Copora lutea, total implants, percentage of live foetuses per litter, foetal body weights and incidence of external or visceral malformations were unaffected by treatment. There was, however,

a significant increase in two skeletal variations in the 3,549 mg/kg group. The NOAELs for maternal and developmental toxicity were considered to be 3,549 mg/kg/day (Tyl et al., 1995b) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The NOAEL from a 24-month rat dietary study was reported to be 200 mg/kg/day based on kidney lesions in male F344 rats at 1,000 mg/kg/day (DePass et al., 1986b). A subsequent 12-month rat dietary study using male Wistar rats reported a NOAEL of 150 mg/kg/day also based on kidney toxicity at 300 mg/kg/day and higher (Corley et al., 2008). The Wistar rat strain was shown to be more sensitive (approximately three-fold) to the kidney toxicity of ethylene glycol than F344 rats (Cruzan et al., 2004). The NOAEL of 150 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Snellings et al. (2013) derived an oral reference dose for ethylene glycol using benchmark dose modelling, with toxicokinetic (PBPK modelling) and toxicodynamic data. The human equivalent dose ($[BMDL_{05}]_{HED}$) was calculated to be 150 mg/kg/day.

Oral RfD = $[BMDL_{05}]_{HED}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 1
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 150/(1 x 10 x 1 x 1 x 1) = 150/10 = 15 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (15 x 70 x 0.1)/2 = 53 mg/L

B. Cancer

Ethylene glycol was not carcinogenic to rats and mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ethylene glycol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on ethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	>72,860	1	Pillard (1995)
Oncorhynchus mykiss	96-hour LC_{50}	22,810 24,591	2	OECD (2004a,b)
Daphnia magna	48-hour EC_{50}	>100	1	ECHA
Daphnia magna	48-hour EC_{50}	46,300	2	Gersich et al. (1986)
Ceriodaphnia dubia-affinis	48-hour EC_{50}	25,800 (20°C) 10,000 (24°C)	2	Cowgill et al. (1985)
Daphnia magna	48-hour EC_{50}	46,300 (20°C) 51,000 (24°C)	2	Cowgill et al. (1985)
Selenastrum capricornutum	96-hour IC_{50} NOEC	10,940 10,000	2	Pillard and DuFresne (1999)

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies conducted on ethylene glycol.

Table 4: Chronic Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	7-day NOEC	15,380	2	Pillard (1995)
Ceriodaphnia dubia	7-day NOEC (reproduction)	8,590	2	Pillard (1995)
Pseudokirchneriella subcapitata	72-hr NOEC	>100 *	2	ECHA

*Read-across to pentaethylene glycol (CAS No. 4792-15-8)

C. Terrestrial Toxicity

No guideline studies have been conducted on ethylene glycol.

D. Calculation of PNEC

The PNEC calculations for ethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (22,810 mg/L), *Daphnia* (>100 mg/L), and algae (10,940 mg/L). NOEC values from long-term studies are available for fish (15,380 mg/L), invertebrates (8,590 mg/L) and algae (10,000 mg/L). On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported E(L)C_{50} value of 100 mg/L for fish. The E(L)C_{50} value is used because the value for fish is lower than the NOEC values for all three trophic levels. The $PNEC_{aquatic}$ is 10 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.4 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.82/1280) \times 1000 \times 10$
$= 6.4$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.82\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.13 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 10

= 0.13 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ethylene glycol is readily biodegradable and thus does not meet the screening criteria for persistence.

The measured BCF in fish is 10. Thus, ethylene glycol does not meet the criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on ethylene glycol are > 0.1 mg/L. The acute $E(L)C_{50}$ values from the acute aquatic toxicity studies on ethylene glycol are > 1 mg/L. Thus, ethylene glycol does not meet the criteria for toxicity.

The overall conclusion is that ethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

STORE Category 2 (target organ: kidney)

B. Labelling

Warning

A. Pictogram



IX. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention.

Ingestion

Rinse mouth with water and then drink a glass of water. Get medical attention. Never give anything by mouth to an unconscious person.

Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

B. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Handle in accordance with good industrial hygiene and safety practice.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

For large amounts: dike spillage and pump off product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

C. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

D. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standards for ethylene glycol in Australia is as follows: 10 mg/m^3 as an 8-hour TWA for ethylene glycol (particulate); 20 ppm (52 mg/m^3) as an 8-hour TWA for ethylene glycol (vapour). There is also a skin notation indicating that absorption through the skin may be significant source of exposure.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

X. TRANSPORT INFORMATION

Ethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Blood, F.R. (1965). Chronic toxicity of ethylene glycol in the rat. Food Cosmet. Toxicol. 3: 229-234.

Carney, E.W., Pottenger, L.H., Bartels, M.J., Jaeckh, R., and Quast, J.F. (1998). Comparative pharmacokinetics and metabolism of ethylene glycol in pregnant rats and rabbits. Toxicol. Lett. 95: 208.

Chapin, R.E. and R.A. Sloane. (1997). Reproductive assessment by continuous breeding: evolving study design and summaries of ninety studies. Environ Health Perspect. 1997 Feb; 105(Suppl 1): 199–205.

Corley, R.A., Meek, M.E., and Carney, E.W. (2005a). Mode of action: oxalate crystal-induced renal tubule degeneration and glycolic acid-induced dysmorphogenesis – renal and developmental effects of ethylene glycol. Crit. Rev. Toxicol. 35: 691-702.

Corley, R.A., Bartels, M.J., Carney, E.W., Weitz, K.K., Soelberg, J.J., and Gies, R.A. (2005b). Development of a physiologically based pharmacokinetic model for ethylene glycol and its metabolite, glycolic acid, in rats and humans. Toxicol. Sci. 85: 476-490.

Corley, R.A., Wilson, D.M., Hard, G.C., Stebbins, K.E., Bartels, M.J., Soelberg, J.J., Dryzga, M.D., Gingell, K.E and Snellings, W.M.(2008). Dosimetry considerations in the enhanced sensitivity of male Wistar rats to chronic ethtlene glocol-induced nephrotoxicity. Toxicology and Applied Pharmacology. Volume 228, Issue 2: 165-178.

Cowgill, U.M., Takahash, I.T., and Applegath, S.L. (1985). A comparison of the effect of four benchmark chemicals on Daphnia magna and Ceriodaphnia dubia-affinis tested at two different temperatures. Environ. Toxicol. Chem. 4: 415-422.

Cruzan, G., Corley, R.A., Hard, G.C., Mertens, J.J., McMartin, K.E., Snellings, W.M., Gingell, R., and Deyo, J.A. (2004). Subchronic toxicity of ethylene glycol in Wistar and F-344 rats related to metabolism and clearance of metabolites. Toxicol Sci. 81: 502-11.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DePass, L.R., Garman, R.F., Woodside, M.D., Giddens, W.E., Maronpot, R.R., and Weil, C.S. (1986a). Chronic toxicity and oncogenicity studies of ethylene glycol in rats and mice. Fundam. Appl. Toxicol. 7: 547-565.

DePass, L.R., Woodside, M.D., Maronpot, R.R., and Weil, C.S. (1986b). Three-generation reproduction and dominant lethal mutagenesis studies with ethylene glycol in the rat. Fundam. Appl. Toxicol. 7: 566-572.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Evans, W.H., and David, E.J. (1974). Biodegradation of mono-, di-, and triethylene glycols in river waters under controlled laboratory conditions. Water Res. 8: 97-100.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996a). Pharmacokinetics of ethylene glycol. I. Plasma disposition after single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Drug Metab. Dispos. 24: 911-921.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996b). Pharmacokinetics of ethylene glycol. II. Tissue distribution, dose dependent elimination, and identification of urinary metabolites following single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Xenobiotica 26: 1195-1220.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. Chemosphere 14: 1589-1616.

Gersich, F.M., Blanchard, F.A., Applegath, S.L., and Park, C.N. (1986). The precision of Daphnid (Daphnia magna Straus, 1820) static acute toxicity tests. Arch. Environ. Contam. Toxicol. 15: 741-749.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Science 4: 67-80.

Hardin, B.D., Schuler, R.L., Burg, J.R., Booth, G.M., Hazelden, K.P., MacKenzie, K.M., Piccirillo, V., Jr, and Smith, K.N. (1987). Evaluation of 60 chemicals in a preliminary developmental toxicity test. Terat. Carcinogen. Mutagen. 7: 29-48.

Harris, M.W., Chapin, R.E., Lockhart, A.C., and Jokinen, M.P. (1992). Assessment of a short-term reproductive and developmental toxicity screen. Fundam. Appl. Toxicol. 19: 186-196.

Hess, R., Bartels, M.J., and Pottenger, L.H. (2004). Ethylene glycol: an estimate of tolerable levels of exposure based on a review of animal and human data. Arch. Toxicol. 78: 671-680.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Kurihara, A., Manabe, A., Katsuno, K., Itoh, K., Hisamitsu, H., Wakumoto, S., and Yoshida, T. (1996). Evaluation of skin irritation and sensitization of two diol solutions used as experimental dentin primers in humans and guinea pigs. Dent. Mater. J., 15: 226-232.

Lamb, J.C., IV, Maronpot, R.R., Gulati, D.K., Russel, V.S., Hommel-Barnes, L., and Sabharwa, l. P.S. (1985). Reproductive and developmental toxicity of ethylene glycol in the mouse. Toxicol. Appl. Pharmacol. 81: 100-112.

McGregor, D.B., Brown, A.G., Howgate, S., McBride, D., Riach, C., and Caspary, W.J. (1991). Responses of the L5178Y mouse lymphoma cell forward mutation assay. V: 27 coded chemicals. Environ. Mol. Mutagen. 17: 196-219.

Melnick, R.L. (1984). Toxicities of ethylene glycol and ethylene glycol monoether in Fischer 344/N rats and B6C3F1 mice. Environ. Health Perspect. 57: 147-155.

Neeper-Bradley, T.L., Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco P.E. (1995). Determination of a no-observed-effect level for developmental toxicity of ethylene glycol administered by gavage to CD rats and CD-1 mice. Fundam. Appl. Toxicol. 27: 121-130.

National Toxicology Program [NTP]. (1993). Toxicology and Carcinogenesis Studies of Ethylene Glycol in B6C3F1 Mice (Feed Studies). National Toxicology Program Technical Report Series No. 413.

OECD. (2004a). SIDS Dossier on the HPV Chemical Ethylene Glycol (CAS No. 107-21-1).

OECD. (2004b). SIDS Initial Assessment Report on the Ethylene Glycol Category: Ethylene Glycol (CAS No. 107-21-1), Diethylene Glycol (CAS No. 111-46-6), Triethylene Glycol (CAS No. 112-27-6), Tetraethylene Glycol (CAS No. 112-60-7), Pentaethylene glycol (CAS No. 4792-15-8).

Pillard, D. (1995). Comparative toxicity of formulated glycol deicers and pure ethylene and propylene glycol to Ceriodaphnia dubia and Pimephales promelas. Environ. Toxicol. Chem. 14: 311-315.

Pillard, D.A. and DuFresne, D.L. (1999). Toxicity of formulated glycol deicers and ethylene and propylene glycol to lactuca sative, lolium perenne, selenastrum capricornutum, and lemna minor. Arch Environ. Contam. Toxicol. 37(1):29-35.

Price, C.J., Kimmel, C.A., Tyl, R.W., and Marr, M.C. (1985). The developmental toxicity of ethylene glycol in rats and mice. Toxicol. Appl. Pharmacol. 81: 113-127.

Robinson, M., Pond, C.L., Laurie, R.D., Bercz, J.P., Henningsen, G., and Condie L.W. (1990). Subacute and subchronic toxicity of ethylene glycol administered in drinking water to Sprague-Dawley rats. Drug Chem. Toxicol .13: 43-70.

Schuler, R.L., Hardin, B.D., Niemeier, R.W., Booth, G., Hazelden, K., Piccirillo, V., and Smith, K. (1984). Results of testing 15 glycol ethers in a short-term in vivo reproductive toxicity assay. Environ. Health Perspect. 57: 141-146.

Snellings, W.M., Corley, R.A., McMartin, K.E., Kirman, C.R., and Bobst, S.M. (2013). Oral reference dose for ethylene glycol based on oxalate crystal-induced renal tubule degeneration as the critical effect. Regul. Toxicol. Pharmacol. 65: 229-241.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P. (2007). A review of large granular lymphocytic leukemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Fait, D.L., Savine, T.A., Dodd, D.E., Klonne, D.R., and Pritts, I.M. (1995a). Evaluation of the developmental toxicity of ethylene glycol aerosol in the CD rat and CD-1 mouse by whole-body exposure. Fundam. Appl. Toxicol. 24: 57-75.

Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco, P.E. (1995b). Assessment of the developmental toxicity of ethylene glycol applied cutaneously to CD-1 mice. Fundam. Appl. Toxicol. 27: 155-166.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Dodd, D.E., Klonne, D.R., Pritts, M., and Losco, P.E. (1995c). Evaluation of the developmental toxicity of ethylene glycol aerosol in CD-1 mice by nose-only exposure. Fundam. Appl. Toxicol. 27: 49-62.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Waggy, G.T., Conway, R.A., Hansen, J.L., and Blessing, R.I. (1994). Comparison of 20-d BOD and OECD closed-bottle biodegradation tests. Environ. Toxicol. Chem. 13: 1277-1280.

SODIUM HYDROXIDE

This dossier on sodium hydroxide presents the most critical studies pertinent to the risk assessment of sodium hydroxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the OECD-SIDS documents on sodium hydroxide (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydroxide

CAS RN: 1310-73-2

Molecular formula: HNaO

Molecular weight: 40 g/mol

Synonyms: Caustic soda, soda lye, NaOH

SMILES: O[Na]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Sodium Hydroxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	Lide, 2009; ECHA
Melting Point	318°C (solid, 100%); 52°C (60% solution)	2	ECHA
Boiling Point	1,388°C @ 101.3 kPa	2	Lide, 2009; ECHA
Density	2130 kg/m^3, 20°C (100%) 1430 kg/m^3, 20°C (40%)	2	Lide, 2009; ECHA
Vapour Pressure	1 Pa @ 513°C	2	Lide, 2009; ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble (>10 g/L @ 25°C)	2	Lide, 2009; ECHA
Dissociation Constant (pKa)	14.8 @ 25°C	2	Lide, 2009; ECHA
pH of 5% NaOH solution	14	2	O'Neil, 2006

Sodium hydroxide (NaOH) is a strong alkaline substance that dissociates completely in water to sodium (Na^+) and hydroxyl (OH^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility and low vapour pressure, sodium hydroxide will be found predominantly in the aquatic environment where it dissociates completely to sodium (Na^+) and hydroxyl (OH^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of sodium hydroxide to an aquatic ecosystem may increase the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of sodium hydroxide into the aquatic environment from the use of NaOH could potentially increase the sodium concentration and the pH in the aquatic environment. Table 2 shows the concentration of sodium hydroxide needed to increase the pH to values of 9.0, 10.0, 11.0 and 12.0.

Table 2: Sodium Hydroxide Concentration (mg/L) Needed to Increase pH (DeGroot et al., 2002; taken from OECD, 2002b)

Buffer capacity*	Final pH			
	9.0	10.0	11.0	12.0
0 mg/L HCO_3 (distilled water)	0.4	4.0	40	400
20 mg/L HCO_3 (10th percentile of 77 rivers)	1.0	8.2	51	413
106 mg/L HCO_3^- (mean value of 77 rivers)	3.5	26	97	468
195 mg/L HCO_3^- (90th percentile of 77 rivers)	6.1	45	145	525

*The initial pH of a bicarbonate solution with a concentration of 20-195 mg/L was 8.25 to 8.35.

Na^+ and OH^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Limited toxicity data exist for sodium hydroxide (NaOH). Depending on the concentration, solutions of NaOH are corrosive, irritating or non-irritating. These solutions cause direct effects to the skin, eyes, respiratory tract and gastrointestinal tract. Vapours from aqueous solutions of KOH can cause respiratory irritation. NaOH is not a skin sensitiser. There are no repeated dose, reproductive and developmental toxicity studies on sodium hydroxide.

B. Toxicokinetics/Metabolism

Sodium hydroxide dissociates completely in aqueous solutions to sodium (Na^+) and hydroxyl (OH^-) ions. Sodium is an essential nutrient involved in fluid and electrolyte balance and is required for normal cellular function (Ganong, 1995). Sodium is the major extracellular cation in the body; the total body content is tightly regulated (Ganong, 1995).

C. Acute Toxicity

There are no oral toxicity guideline studies on sodium hydroxide. An oral LD_{50} of a 1 to 10% solution of NaOH in rabbits was reported to be 325 mg/kg (expressed as 100% NaOH) (OECD, 2002a,b). Mortality was also observed when a 1% NaOH solution was dosed, but in this case, the applied volume was relatively high (24 mL per kg body weight) (OECD, 2002a,b).

Acute toxicity studies were not identified for the inhalation and dermal route.

D. Irritation

Animal studies have shown that an 8% NaOH solution is corrosive to the skin. In humans, 0.5 to 4% NaOH concentrations produced skin irritation; and, based on the results of two different human patch tests, a NaOH solution that is slightly less than 0.5% would be non-irritating to human skin (OECD, 2002a,b).

Results from animal eye irritation studies indicate that a 0.2-1.0% NaOH solution would be non-irritating, while 1.2 or > 2% NaOH solutions would be corrosive (OECD, 2002a,b).

E. Sensitisation

Male volunteers were exposed on the skin of their back to solutions of 0.063 to 1.0% NaOH in the induction phase of a human patch test. After 7 days the volunteers were challenged to a concentration of 0.125% NaOH. The irritant response correlated well with the concentration of NaOH, but an increased response was not observed when the previously patch tested sites were re-challenged. Based on this study, sodium hydroxide is not a skin sensitiser (OECD, 2002a,b; ECHA) [Kl. score = 2].

F. Repeated Dose Toxicity

No studies were identified for the oral and dermal route. An inhalation study was conducted in rats exposed to aerosols of solutions of NaOH ranging from 5% to 40%. Exposures were twice weekly (hours/day and total exposure days unspecified). All animals in the 40% solution group died within a month mostly from bronchopneumonia. At the lower concentrations, respiratory tract lesions were observed; an NOAEL was not identified (NIOSH, 1975).

G. Genotoxicity

In Vitro Studies

Several *in vitro* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

In Vivo Studies

Several *in vivo* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

H. Carcinogenicity

No studies were identified.

I. Reproductive Toxicity

No valid studies were identified regarding toxicity to reproduction in animals after oral, dermal or inhalation exposure to NaOH.

J. Developmental Toxicity

No valid studies were identified regarding developmental toxicity in animals after oral, dermal or inhalation exposure to NaOH (OECD, 2002a,b; ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Oral and dermal repeated dose, reproductive, and developmental toxicity studies have not been conducted on NaOH. A repeated dose toxicity study was conducted by the inhalation route, but the methodology and documentation preclude its use for deriving a toxicological reference value. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of NaOH, which would limit the amount absorbed. NaOH dissociates to sodium and hydroxyl ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, a toxicological reference value was not derived for NaOH.

The Australian drinking water guideline values for sodium (180 ppm, aesthetic) and pH may be applicable (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium hydroxide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium hydroxide has low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

The OECD-SIDS SIAR on NaOH states that while the toxicity of the NaOH has been assumed to be related to the hydroxyl anion, in general a pH change could influence the speciation of other chemicals and therefore increase and/or decrease toxicity of the substance.

There are no guideline studies on NaOH; the studies summarised below have Klimisch scores of 3 or 4.

Acute Fish

The 24-hour LC_{50} to *Carassius auratus* (goldfish) is 160 mg/L. At 100 mg/L, which was equivalent to a pH of 9.8, no mortality was observed. The 48-hour LC_{50} to *Leuciscus idus melanotus* is 189 mg/L. The 96-hour LC_{50} of *Gambusia affinis* (mosquitofish) is 125 mg/L. At 84 mg/L, no effects on the fish were observed. The pH was 9 at 100 mg/L.

Acute Invertebrate

The 48-hour LC_{50} is 40 mg/L for *Ceriodaphnia cf. dubia*. The toxicity threshold concentration of NaOH for *Daphnia magna* was reported to range from 40 to 240 mg/L.

Acute Algae

No studies were identified.

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

The OECD-SIDS SIAR on NaOH states the following regarding the aquatic toxicity studies on NaOH (OECD, 2002b):

> *"In many cases pH, buffer capacity and/or medium composition were not discussed in the publications, although this is essential information for toxicity tests with NaOH. This is the most important reason why most of the studies, mentioned above were considered invalid. Although valid acute ecotoxicity tests and chronic ecotoxicity tests with NaOH are not available, there is no need for additional testing with NaOH. A significant number of acute toxicity tests are available, and the results of the tests are more or less consistent. Altogether they give a sufficient indication of acute toxicity levels of sodium hydroxide."*
>
> *"Furthermore, acute toxicity data cannot be used to derive a PNEC or a PNEC added for sodium hydroxide. Aquatic ecosystems are characterised by an alkalinity/pH, and the organisms of the ecosystem are adapted to these specific natural conditions. Based on the natural alkalinity of waters, organisms will have different optimum pH conditions, ranging from poorly buffered waters with a pH of 6 or less to very hard waters with pH values up to 9. A lot of information is available about the relationship between pH and ecosystem structure and also natural variations in pH of aquatic ecosystems have been quantified and reported extensively in ecological publications and handbooks."*
>
> *"Normally a PNEC or a PNEC added has to be derived from the available ecotoxicity data. A PNEC added is a PNEC which is based on added concentrations of a chemical (added risk approach). Based on the available data it is not considered useful to derive a PNEC or a PNEC added for NaOH because:*
>
> - *The natural pH of aquatic ecosystems can vary significantly between aquatic ecosystems,*

- *Also, the sensitivity of the aquatic ecosystems to a change of the pH can vary significantly between aquatic ecosystems and*
- *The change in pH due to an anthropogenic NaOH addition is influenced significantly by the buffer capacity of the receiving water."*

"Although a PNEC or a PNEC added was not calculated for NaOH, there is a need to assess the environmental effect of a NaOH (alkaline) discharge. Based on the pH and buffer capacity of effluent and receiving water and the dilution factor of the effluent, the pH of the receiving water after the discharge can be calculated. Of course, the pH change can also be measured very easily via a laboratory experiment or by conducting field measurements. The change in pH should be compared with the natural variation in pH of the receiving water and based on this comparison it should be assessed if the pH change is acceptable."

Based on the information above, PNEC values for freshwater, sediment, and soil were not derived for sodium hydroxide.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium hydroxide is an inorganic salt that dissociates completely to sodium and hydroxide ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and hydroxide ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Sodium and hydroxide ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, sodium hydroxide is not expected to bioaccumulate and does not meet the screening criteria for bioaccumulation.

No chronic toxicity data exist on sodium hydroxide; however, the acute EC_{50} values are > 1 mg/L in fish, invertebrates and algae. Thus, sodium hydroxide does not meet the screening criteria for toxicity.

The overall conclusion is that sodium hydroxide is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Metal Corrosive Category 1

Skin Corrosive, Category 1A

Eye Damage, Category 1

EU Concentration Limits:
≥ 5%: Skin Corrosive 1A
≥ 2 to <5%: Skin Corrosive 1B

≥ 0.5%to <2%: Skin Irritant Category 2
≥ 0.5% to <2%: Eye Irritant Category 2

In addition to the hazard statements corresponding the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

C. Pictograms



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Flush with plenty of fresh water for 15 minutes holding eyelids open, lifting eyelids occasionally to ensure complete removal of the product. Remove contacts, if present and easy to do. DO NOT allow rubbing of eyes or keeping eyes closed. Seek medical attention.

Skin Contact

Rinse with soap and plenty of water for several minutes. Remove contaminated clothing. Seek medical attention immediately.

Inhalation

Remove person to fresh air. Apply artificial respiration if not breathing. Seek medical attention.

Ingestion

Rinse mouth with water (only if the person is conscious), but do not administer fluids. Do NOT induce vomiting. Seek medical attention immediately.

B. Fire Fighting Information

Extinguishing Media

Carbon dioxide, water spray, foam, dry chemical.

Specific Exposure Hazards

Containers may explode when heated. May form explosive mixtures with strong acids. Hazardous combustion products may include the following materials: halogenated compounds, metal oxides/oxides, sodium monoxide.

Special Protective Equipment for Firefighters

Full protective clothing and approved self-contained breathing apparatus required for firefighting personnel.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment and avoid direct contact. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Ventilate the area before entry.

Environmental Precautions

Prevent spills from entering storm drains or sewers and contact with soil.

Steps to be Taken if Material is Released or Spilt

Use an absorbent material to recover as much product as possible, then rinse the affected area with water to dilute the residue. Disposal of leftover product and used containers should be carried out in accordance with all local, state and federal regulations.

D. Storage and Handling

General Handling

Wear appropriate personal protective equipment. Avoid contact with eyes, skin or clothing. Avoid breathing mist, vapours or spray. Use only with adequate ventilation. Wash hands after use. Launder contaminated clothing.

Storage

Store away from acids. Keep container closed when not in use. Store in a cool well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for sodium hydroxide in Australia is 2 mg/m^3 as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: Use a mask or approved air-purifying respirator with appropriate cartridge or canister in spray applications or in confined spaces.

Hand Protection: Wear impervious gloves to prevent skin contact and absorption of this material. Rubber or Neoprene gloves may afford adequate skin protection.

Skin Protection: Wear appropriate clothes (i.e., coveralls). Use non-slip footwear.

Eye Protection: Wear eye protection in situations where splash or thick mists are possible.

Other Precautions: Avoid contact with skin, eyes and clothing. When using, do not eat or drink. Wash hands thoroughly with soap and water before eating or drinking. Remove contaminated clothing and launder before reuse.

F. Transport Information

For sodium hydroxide solutions of > 5%:
Australian Dangerous Goods
UN1824, Corrosive liquid, (Sodium hydroxide solution)
Class 8
Packing Group: II

Lower concentrations of sodium hydroxide may require a different packing group or may not require any hazard code if the concentration of NaOH is low enough not to be considered a corrosive material.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

De Groot et al. (2002). The addition of sodium hydroxide to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals Int. Doc. No. 8320/47/01; cited in OECD, 2002a,b.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

NIOSH. (1975). National Institute of Occupational Safety and Health: Criteria Document: Sodium Hydroxide p.46 (1975) DHEW Pub. NIOSH 76-105; cited in NICNAS IMAP assessment report for sodium hydroxide, https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1406#cas-A_1310-73-2.

O'Neil, M.J. [Ed.]. (2006). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. P. 1485, Whitehouse Station, NJ: Merck and Co., Inc.

OECD. (2002a). IUCLID Data Set for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

2-PROPENOIC ACID, POLYMER WITH SODIUM PHOSPHINATE (1:1), SODIUM SALT

This dossier on 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt in coal seam gas extraction activities. The majority of information presented in this dossier is based on a surrogate 2-propenoic acid, polymer with sodium phosphinate (CAS No. 71050-62-9). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt

CAS RN: 129898-01-7

Molecular formula: $(C_3H_4O_2.H_3O_2\text{-}P.Na)_x$- x-Na

Molecular weight: Variable

Synonyms: 2-propenoic acid, polymer with sodium phosphinate, sodium salt; 2-propenoic acid polymer with sodium hypophosphite, sodium salt; 2-Propenoic acid, polymer with sodium hypophosphite, sodium salt

SMILES: Not applicable

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of 2-Propenoic acid, Polymer with Sodium Phosphinate (CAS No. 71050-62-9)

Property	Value	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	BWA, 2006
Melting Point	-1 to -3°C	BWA, 2006
Boiling Point	101 to 103°C	BWA, 2006
Specific Gravity	1.20 to 1.24	BWA, 2006
pH	3.5 to 4.5	BWA, 2006
Viscosity	75-200 mm^2/s @ 25°C	BWA, 2006
Water Solubility	Miscible	BWA, 2006

III. ENVIRONMENTAL FATE PROPERTIES

In an OECD 301E test, 2-propenoic acid, polymer with sodium phosphinate degraded 20% in 28 days, indicating that it is not readily biodegradable (BWA, 1999).

As a polymer, 2-propenoic acid, polymer with sodium phosphinate is not expected to bioaccumulate, because its molecular weight will limit its bioavailability.

IV. HUMAN HEALTH HAZARD ASSESSMENT

There is very limited information on 2-propenoic acid, polymer with sodium phosphinate.

A technical data sheet on Belsperse® 164 Dispersant (active ingredient: CAS No. 71050-62-9) lists this product as having an acute oral LD_{50} value of > 5,000 mg/kg in rats. The product is non-irritating to the skin and eyes (BWA, 2006).

In a letter to the U.S. EPA, male and female rats dosed by oral gavage with a 40% solution of this polymer showed treatment-related signs of osteomalacia associated with hyperphosphaturia and calciuria by week 8 of a 90-day study (U.S. EPA, 2016a).

The U.S. EPA TSCATS database also has a brief summary of a 4-week rat oral gavage conducted on the product BELSPERSE 164 (CAS No. 71050-62-9). At 5,000 mg/kg/day, there were adverse clinical signs, gross organ pathology and changes in blood biochemical parameters. The NOAEL was 2,000 mg/kg/day (U.S. EPA, 2016b).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on 2-propenoic acid, polymer with sodium phosphinate is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this polymer.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2-Propenoic acid, polymer with sodium phosphinate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2-Propenoic acid, polymer with sodium phosphinate exhibits low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on 2-propenoic acid, polymer with sodium phosphinate.

Table 2: Acute Aquatic Toxicity Studies on 2-Propenoic Acid, Polymer with Sodium Phosphinate (CAS No. 71050-62-9)

Test Species	Endpoint	Results (mg/L)	Reference
Rainbow trout	96-hour LC_{50}	> 1,000	BWA, 2006
Zebra fish	96-hour LC_{50}	> 1,000	BWA, 2006
Daphnia	24-hour EC_{50}	320	BWA, 2006
Algae	72-hour EC_{50}	130	BWA, 2006

Chronic Studies

No studies were located.

C. Terrestrial Toxicity

No studies were located.

D. Calculation of PNEC

The PNEC calculations for 2-propenoic acid, polymer with sodium phosphinate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (> 1,000 mg/L), *Daphnia* (> 320 mg/L) and algae (> 130 mg/L). No long-term studies on 2-propenoic acid, polymer with sodium phosphinate are available. On the basis of the short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 130 mg/L for algae. The $PNEC_{water}$ is 0.13 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot estimate using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$.

PNEC soil

There are no toxicity data for soil-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot be estimated using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Based on the information for read-across substance 2-Propenoic acid, polymer with sodium phosphinate, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not readily biodegradable. Thus, it meets the screening criteria for persistence.

Read-across substance 2-Propenoic acid, polymer with sodium phosphinate is a high molecular weight polymer that is not expected to be bioavailable to aquatic or terrestrial organisms. Thus, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt it is not expected to bioaccumulate.

No chronic aquatic toxicity studies have been conducted on read-across substance 2-propenoic acid, polymer with sodium phosphinate. The acute E(L)C_{50} values are > 1 mg/L. Thus, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt does not meet the screening criteria for toxicity.

The overall conclusion is that 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, phosphorus oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing closed work clothing is recommended.

F. Transport Information

2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BWA. (1999). BWA Water Additives. Belsperse® 164 Dispersant. General Product Information,

BWA. (2006). BWA Water Additives. Product Information for Belsperse 164 – High Performance Dispersant for Industrial Water Systems. 2006 BWA, V1010

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. EPA [EPA]. (2016a). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88900000038; accessed October 2016.

U.S. EPA [EPA]. (2016b). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88920001980; accessed October 2016.

GLUTARALDEHYDE

This dossier on glutaraldehyde presents the most critical studies pertinent to the risk assessment of glutaraldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from NICNAS (1994) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Glutaraldehyde

CAS RN: 111-30-8

Molecular formula: $C_7H_8O_2$

Molecular weight: 100.12 g/mol

Synonyms: Pentanedial; glutaral; glutaric dialdehyde; 1,3-diformylpropane; 1,5-pentanedial; glutaric aldehyde; glutaric acid dialdehyde; dioxopentane; glutardialdehyde; 1,5-pentanedione; Algicide®C

SMILES: C(CC=O)CC=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Glutaraldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	Sweetish smelling, clear water liquid	1	ECHA
Melting Point*	-33°C (pressure not provided)	1	ECHA
Boiling Point*	101.5°C @ 98.71 kPa	1	ECHA
Density*	1,130 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure*	21 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})*	-0.36 @ 23°C and pH 7	1	ECHA
Water Solubility*	Miscible @ 20°C	2	ECHA
Flash Point*	Not measurable	1	ECHA
Auto flammability*	395°C @ ~1,000hPa	1	ECHA
Viscosity*	12.75 mm^2/s (static) at 25°C	1	ECHA
Henry's Law Constant	0.011 Pa m^3/mol at 25°C [QSAR]	2	ECHA

*ca. 50% glutaraldehyde solution (in water)
1 ppm = 4.095 mg/m3
1 mg/m3 = 0.244 ppm

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Glutaraldehyde is considered readily biodegradable. It is also expected to have a low potential for bioaccumulation. The K_{oc} values for glutaraldehyde indicate that it will have low potential for adsorption to suspended solids and sediment in water and moderate adsorption to soil. Glutaraldehyde is not expected to undergo hydrolysis in the environment. Overall, glutaraldehyde shows limited persistence in the environment.

B. Partitioning

In an OECD TG 111 test (hydrolysis as a function of pH), glutaraldehyde was hydrolytically stable at pH 4 and pH 7 but decomposed at pH 9 (ECHA) [Kl. score = 2].

Photolytic degradation of glutaraldehyde occurred in water under sensitised conditions: the half-life was 18 days when equivalent to 36 days of natural sunlight (12 hours/day; sensitised acetone system); and 49 days when equivalent to 34 days of natural sunlight (12 hours/day; sensitised acetonitrile system). There was no photodegradation of glutaraldehyde under darkness or non-sensitised conditions (ECHA) [Kl. score = 2].

C. Biodegradation

Glutaraldehyde was considered readily biodegradable in an OECD 301A (DOC die away test). Degradation was 90-100% in 28 days (ECHA) [Kl. score = 1].

In a simulation test involving aerobic sewage treatment [activated sludge units] (OECD TG 303A), glutaraldehyde degraded 97% after 73 days based on DOC removal (ECHA) [Kl. score = 1].

In an aerobic aquatic metabolism test, [^{14}C]-glutaraldehyde had a half-life of 10.6 hours in the water/sediment system. A minor transformation product was glutaric acid: the maximum yield was 18.9 to 21.5% at 12 hours, which then declined rapidly to 10.1 to 11% by 24 hours; and was not observed at the end of the study period in the aqueous phase (ECHA) [Kl. score = 1].

In an anaerobic aquatic metabolism test, [^{14}C]-glutaraldehyde was rapidly metabolised with the first-order half-life being 7.7 hours. Glutaraldehyde was transformed to 5-hydroxypentanal (ca 37% of applied radioactivity) on day 1; after that, it declined to < 10%; it was not detected at all after 30 days. The second stable transformation product was 1,5-pentanediol (35% of radioactivity on Day 1), which accounted for 70% of the radioactivity at the end of the test. A minor transformation product was a compound formed via Aldol condensation, cyclisation and dehydration. This compound accounted for about 10-20% of total radioactivity from Day 1 onwards (ECHA) [Kl. score = 1].

In an aerobic soil metabolism test, the half-life of the degradation of [^{14}C]-glutaraldehyde was calculated to be 1.7 days, indicating rapid degradation in soil by microbial biotransformation. Degradation products were measured but not identified (ECHA) [Kl. score = 1].

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

The organic carbon/water partition coefficients (K_{oc}) values were determined for sediment and four types of soil. The values are as follows: 120 for sediment; 210 for sandy loam; 500 for silty clay loam; 340 for silt loam; and 460 for loamy sand (ECHA; Leung, 2001) [Kl. score = 1].

Based on these K_{oc} values, glutaraldehyde is considered to be moderately mobile in soil. If released to water, based on these K_{oc} values and its water solubility, it has moderate potential for adsorption to suspended solids or sediments.

E. Bioaccumulation

Glutaraldehyde is not expected to bioaccumulate. The measured log K_{ow} at pH 5, 7 and 9 are -0.41, -0.36 and -0.80, respectively (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has moderate-to-high acute toxicity by the oral route, low-to-moderate toxicity by the dermal route, and moderate-to-high toxicity by the inhalation route. Acute inhalation exposure may cause respiratory irritation. Glutaraldehyde is corrosive to the skin and eyes; it is also a skin and respiratory sensitiser. Repeated oral exposures via drinking water to rats have resulted in general systemic toxicity, but no target organ effects. In contrast, the upper respiratory tract, particularly the nasal cavity, is the target organ in rodents from repeated inhalation exposure. Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. Glutaraldehyde is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity.

B. Toxicokinetics

Dermal Absorption

[1,5-^{14}C]-glutaraldehyde was applied to the skin of male and female F344 rats. Doses were 0.75% and 7.5%: this corresponds to approximately 6.5 and 63 mg/kg for males; and approximately 8.7 and 102 mg/kg for females. The dermal absorption data are presented in Table 2. The results indicate that glutaraldehyde has a low rate of absorption by the dermal route (ECHA).

Table 2: Dermal Absorption Data in Rats on Glutaraldehyde (ECHA)

Sex	Absorption rate constant/hr		% of applied dose	
	Low Dose	High Dose	Low Dose	High Dose
Males	1.5	0.7	0.7	1.3
Females	1.8	0.9	0.3	2.1

An *in vitro* percutaneous absorption study was conducted on glutaraldehyde using excised skin from rats, rabbits, mice, guinea pigs and humans. The skin samples were placed in a flow-through skin penetration chamber, and [^{14}C]-glutaraldehyde was added at doses of 0.75% and 7.5%. The results are presented in Table 3. Glutaraldehyde did not penetrate any of the skin samples to a significant degree, suggesting that only minimal amounts of glutaraldehyde may be available for systemic

uptake and distribution after skin exposure. The results also show that skin absorption was greater for the animal species used in toxicity tests than human skin (ECHA; Frantz et al., 1993).

Table 3: *In vitro* Percutaneous Absorption (mg/cm^2) of Glutaraldehyde (ECHA; Frantz et al., 1993)

Species	Low Dose	High Dose
Animal*	0.006	0.08
Human	0.002	0.02

*Percutaneous absorption in rats, mice, guinea pigs, mice and rabbits were similar to each other and were reported as a single value.

C. Acute Toxicity

The oral LD_{50} values are: 123 to 820 mg/kg in rats; 100 to 352 mg/kg in mice; and 50 mg/kg in guinea pigs (NICNAS, 1994).

The dermal LD_{50} values are: 640 to 2,000 mg/kg in rabbits; > 2,500 mg/kg in rats; and > 4,500 mg/kg in mice (NICNAS, 1994).

The 4-hour inhalation LC_{50} values for glutaraldehyde are listed in Table 4:

Table 4: Acute inhalation LC_{50} values for Glutaraldehyde

Test Material	LC_{50} (males) [mg/L]	LC_{50} (females) [mg/L]	LC_{50} (both sexes) [mg/L]	Reference
50% aq. aerosol	0.52	0.45	-	OECD, 1995
25% aq. aerosol	-	-	0.8	OECD, 1995
50% aq. aerosol	0.35	0.28	-	OECD, 1995
5% soln. vapour	0.096	0.164	-	OECD, 1995

During the exposure period, the animals showed signs of eye and respiratory irritation, as indicated by laboured and audible breathing, and wetness and encrustation around the nose and eyes.

D. Irritation

Glutaraldehyde is corrosive to the skin and eyes of rabbits (NICNAS, 1994; ECHA). Signs of irritation occurred at a concentration of 2% for skin and 0.2% for eyes (NICNAS, 1994). In the acute inhalation studies, rats exposed to aerosols or vapours of glutaraldehyde showed signs of eye and respiratory irritation (OECD, 1995).

E. Sensitisation

Glutaraldehyde is a skin sensitiser to guinea pigs and humans. Information on the individual studies can be found in NICNAS (1994) and in the ECHA REACH database (ECHA).

Asthmatic symptoms, such as wheezing, coughing, chest tightness, breathing difficulties and non-specific hyper-responsiveness have been reported to occur in humans occupationally exposed to glutaraldehyde (NICNAS, 1994). It is unclear whether the asthma is an allergic hypersensitivity response or a result of the aggravation of pre-existing asthma due to the irritating properties of

glutaraldehyde. Nevertheless, glutaraldehyde should be considered a respiratory sensitiser, although one of low potency.

F. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their drinking water 0, 100, 500, or 2,000 ppm glutaraldehyde for 90 days. The approximate daily intakes were 0, 3, 15 or 53 mg/kg/day for males, and 0, 4, 19 or 72 mg/kg/day for females. There were no signs of neurotoxicity at any dose level. There was slight impairment of food consumption in the 2,000 ppm animals, as well as slight impairment of body weight and body weight gain. Impaired water consumption was seen in the 100 and 500 ppm females. The NOAEL for males is 500 ppm (15 mg/kg/day). The NOAEL for females is 100 ppm (4 mg/kg/day) since the impaired water consumption in the 100 ppm females was considered a palatability problem and not an adverse effect (ECHA) [Kl. score = 1].

Male and female F344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 13 weeks. Additional groups of animals were given in their drinking water 0 or 1,000 ppm glutaraldehyde for 13 weeks followed by a 4-week recovery period. The approximate daily intakes were 0, 5, 25 or 100 mg/kg/day for males; and 0, 7, 35 or 120 mg/kg/day for females. Water consumption was reduced in a dose-dependent manner in the $\geq$ 250 ppm males and 1,000 ppm females, which was attributed to an aversion to the taste and/or odour of glutaraldehyde in the water. There was also a reduction in food consumption in the 1,000 ppm animals with a parallel reduction in body weights. It is unclear whether the reduction in food consumption was related to the decreased water consumption. Urine volume was decreased with an increase in specific gravity, along with a slight increase in protein and ketone concentration, in the $\geq$ 250 ppm animals, which was probably related to the decreased water consumption. There were no treatment-related changes in the haematology parameters measured. Blood urea nitrogen was increased in a dose-related manner in the $\geq$ 250 ppm females at the 6-week time point, but not at the 13-week or 17-week time points. Relative kidney weights were increased in a dose-related manner in the $\geq$ 250 ppm males and females and increased absolute kidney weights in the females. Histopathological examination showed no treatment-related effects. The NOAEL is 50 ppm (5 and 7 mg/kg/day for males and females, respectively) based on dose-related increase in kidney weights at $\geq$ 250 ppm (ECHA) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for 12 months. The approximate daily intakes were: 0, 6.4, 30.5, or 116.6 mg/kg/day for males; and 0. 9.6, 46, or 153 mg/kg/day for females. There was no treatment-related mortality. At 2,000 ppm, treatment-related effects included respiratory sounds (both sexes), decrease in body weight (males), decrease in body weight gain (both sexes), decrease in food consumption (both sexes), reduced water consumption (both sexes), lesions within the glandular stomach (both sexes showed erosion/ulceration of the glandular stomach), increased incidence of clear cell foci in the liver (males) and a single case of slight diffuse squamous metaplasia in the epithelium of the larynx (male). At 500 ppm, water consumption was reduced in males which was considered to be a palatability (bad taste) problem and not an adverse effect. No effects were seen in the 100 ppm animals. The NOAEL for this study is 500 ppm, which corresponds to 30.5 and 46 mg/kg/day for males and females, respectively (ECHA) [Kl. score = 1].

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. There were no treatment-related mortalities or clinical symptoms of toxicity. In the 250 and 1,000 ppm groups, there was reduction in

body weight and body weight gain; reduction in food and water consumption; increased statistically significant incidence of nucleated erythrocytes and of large monocytes; decreases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and glutamate dehydrogenase; dose-related decrease in urine volume accompanied by a dose-related increase in osmolality; changes in absolute and relative kidney weight; gastric irritation; increases in bone marrow hyperplasia; and increased incidence of renal tubular pigmentation. The decreased water consumption was considered to be due to the bad taste, smell and/or irritancy of the test substance in the drinking water; thus, it is of no toxicological relevance. As a result of reduced water intake, there are renal physiological adaptation, such as decreased urine, increased osmolality and changes in kidney weight. The haematological and clinical chemistry parameter changes were marginal and were considered to be of no toxicological relevance. The main haematological finding seen at the end of the study, which consisted of the appearance of nucleated erythrocytes and large monocytes in all treated groups (statistically significant for the ≥250 ppm males), was related to the incidence of large granular lymphocytic leukaemia (LGLL) in the spleen. The bone marrow hyperplasia and renal tubular pigmentation are related to the occurrence/incidence of LGLL and were considered by the authors of the study as being secondary to low-grade haemolytic anaemia in animals with LGLL. The NOAEL for this study is 50 ppm which corresponds to 4 and 6 mg/kg/day for males and females, respectively (Van Miller et al., 2002) [Kl. score = 2].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathological lesions in the nasal passages and turbinates were seen at ≥ 0.25 ppm. Treatment-related effects were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing concentration of glutaraldehyde. The NOAEL for this study is 0.125 ppm (Gross et al., 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathologic lesions in the nasal passages and turbinates were seen at all exposure concentrations (≥ 0.0625 ppm). Treatment-related lesions were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing test concentration. Furthermore, neutrophilic inflammation was seen at ≥ 0.062 ppm, and squamous metaplasia as well as necrosis were seen in the larynx at 1 ppm. The LOAEL for this study is 0.0625 ppm; a NOAEL was not established (Gross et al*.,* 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.41 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. Survival was similar between treated and control groups. Hyperplasia of the squamous epithelium lining of the dorsal wall of the nasal passages and the lateral aspect of the atrioturbinate was seen in a greater number of exposed females than in controls. Epidermal erosion and ulceration as well as squamous and inflammatory exfoliation were also seen in the nasal lumens. All of these changes were dependent on the length of

glutaraldehyde exposure. The authors concluded that, since the induced lesions occurred in the more anterior part of the nasal passages, that they were likely the result of an irritation mechanism (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5, or 0.75 ppm (0, 1, 2, or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Mean body weights of all exposed males and the mid- and high-dose females were generally less than those of the controls. Non-neoplastic lesions were limited primarily to the most anterior region of the nasal cavity. Effects included hyperplasia and inflammation of the squamous epithelium; hyperplasia, goblet cell hyperplasia, inflammation and squamous metaplasia of the respiratory epithelium; and hyaline degeneration of the olfactory epithelium. The LOAEL for this study is 0.25 ppm based on hyperplasia and inflammation of the squamous epithelium of the nose in both sexes. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. Mean body weights of the high-dose females were generally lower than the controls. Non-neoplastic lesions were limited primarily to the anterior region of the nasal cavity; the effects were qualitatively similar to those seen in the rats (see accompanying summary on the two-year rat study by van Birgelen et al. [2000]). Squamous metaplasia of the respiratory epithelium was observed in both sexes of mice while female mice also had inflammation and hyaline degeneration of the respiratory epithelium. The incidence and severity grade (in parentheses) of the hyaline degeneration were: 16/50 (1.4), 35/49 (1.4), 32/50 (1.3) and 30/50 (1.1) for the 0, 0.0625, 0.125 and 0.25 ppm dose groups, respectively. The LOAEL for this study is 0.0625 ppm based on hyaline degeneration of the respiratory epithelium in female mice. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Dermal

Applications of a 50% solution of glutaraldehyde was applied to the skin of male and female SD rats for 13 weeks. The doses were 0, 50, 100 and 150 mg/kg glutaraldehyde. At the application site, there were signs of irritation (scabs, desquamation and very slight or well-defined erythema). There was no treatment-related mortality, clinical signs, body weights, feed consumption and ophthalmoscopic effects. There were no changes in the haematology and clinical chemistry parameters that were considered to be biologically or toxicologically relevant. Organ weights were similar between treated and control animals. Histopathological examination showed treatment-related effects in the skin associated with chronic irritation; no other changes were noted that were considered to be treatment-related. The NOAEL for this study is 150 mg/kg, the highest dose tested (ECHA) [Kl. score = 1].

G. Genotoxicity

In Vitro Studies

Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests. The bacterial reverse mutation assays have been the most consistent. Variable results have been reported for the forward gene mutation tests; and for sister chromatid exchange (SCE), chromosomal aberration and Unscheduled DNA Synthesis (UDS) tests (Vergnes and Ballantyne, 2002).

In Vivo Studies

The *in vivo* studies conducted on glutaraldehyde are presented in Table 5. All the studies show that glutaraldehyde is not mutagenic or genotoxic.

Table 5: *In Vivo* Genotoxicity Studies on Glutaraldehyde

Test System	Results*	Klimisch Score	Reference
Rat bone marrow (chromosomal aberration)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Mouse bone marrow (micronucleus)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Drosophila SLRL Test	-	2	ECHA
Rat liver UDS Assay	-	1	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Mouse peripheral blood micronucleus study	-	2	Vernes and Ballantyne (2002)
Rat liver UDS Assay	-	2	Mirsalis *et al.* (1989)

* +, positive; -, negative

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. Mortality rates were 25-30% and 19-23% for males and females, respectively, with no dose-related increase. The major cause of death in all dose groups including the controls was LGLL. There was an increased incidence of LGLL in the liver and spleen in all treated females ($\geq$ 50 ppm). The incidence of LGLL was not significantly increased in the treated males compared to the controls. No other treatment-related increased incidence of tumours was seen (Van Miller et al., 2002) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for two years. The mean daily intake of glutaraldehyde was as follows: 0, 6.1, 31.9 and 120.7 mg/kg/day for males; and 0, 10.5, 48.5 and 176.4 mg/kg/day for females. In the high-dose animals, there was mortality (2 males and 9 females) from asphyxia, and mean terminal body weights were significantly decreased compared to the controls. There were no treatment-related neoplastic effects (ECHA) [Kl. score = 1].

Inhalation

Male and female $B6C3F_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.4 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. No exposure-related neoplastic lesions were observed in either males or females (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5 or 0.75 ppm (0, 1, 2 or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Survival of the treated males was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

I. Reproductive Toxicity

A two-generation reproductive toxicity study was conducted in Wistar rats given 0, 100, 500 and 2,000 ppm glutaraldehyde in their drinking water. The approximately mean daily intake is 0, 12, 58 and 199 mg/kg/day for the parental males and females of the F_0 and F_1 generation during premating. There were no adverse effects on reproductive performance or fertility. Oestrous cycle data, mating behaviour, conception, gestation, parturition, lactation and weaning as well as sperm parameters, sexual organ weights, gross and histopathological findings of these organs were similar between treated and control groups. In the high-dose animals, there was decreased water and/or food consumption; and decreased body weights and/or reduced body weight gains during the premating periods in the F_0 and F_1 parental females during premating, gestation and/or lactation. The high-dose F_1 parental females also had increased the number of erosions/ulcers with microscopic erosion(s) or inflammatory oedema in the mucosa/submucosa of the glandular stomach. There were no adverse effects in the 500 ppm animals except for slight decreases in water consumption due to a palatability (bad taste) problem. Treatment-related signs of developmental toxicity were seen in the progeny of the high-dose F_0 and F_1 parental generation and included impairment in body weight and consequently in organ weights in the respective F_1 and F_2 pups. The NOAEL for reproductive toxicity is 2,000 ppm (199 mg/kg/day), the highest dose tested. The NOAEL for parental systemic toxicity is 500 ppm (58 mg/kg/day). The NOAEL for developmental toxicity is 500 ppm or 58 mg/kg/day (ECHA) [Kl. score = 1].

A two-generation reproductive toxicity study was conducted in Crj: CD(SD) rats given 0, 50, 250 and 1,000 ppm glutaraldehyde in their drinking water. Mean daily intake was not calculated. Parental body weights and body weight gains were significantly reduced at 1,000 ppm at some periods, particularly during pre-mating. Food consumption was significantly reduced at 1,000 ppm for the F_0 and F_1 parental animals during pre-mating and gestation, and F_1 females during lactation. Water consumption was reduced throughout the pre-mating period for the F_0 and F_1 250 and 1,000 ppm parental animals. There was no indication of adverse effects on reproductive performance or fertility at any dose level. For the F_1 1,000 ppm offspring, body weights were reduced from lactation days 21-28. The NOAEL for reproductive toxicity is 1,000 ppm, the highest dose tested. The NOAEL for parental systemic toxicity is 50 ppm. The NOAEL for developmental toxicity is 250 ppm (Neeper-Bradley and Ballantyne, 2000) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Wistar rats were given in their drinking water 0, 50, 250 or 750 ppm (0, 5, 26 or 68 mg/kg) glutaraldehyde from GD 6 to 16. Water consumption was reduced in a dose-related manner in the $\geq$ 250 ppm dams, and was considered not to be a toxic response, but due to the palatability (bad taste) of the drinking test solution. No other maternal effects were seen in the study. There were no significant differences between treated and controls in the sex distribution, placental weights, foetal

weights, malformations or variations. The NOAEL for maternal and developmental toxicity in this study is 68 mg/kg/day, respectively (ECHA) [Kl. score = 1].

Pregnant Wistar rats were dosed by oral gavage with 0, 25, 50 or 100 mg/kg glutaraldehyde on GD 6 to 15. Mortality was significantly increased in the high-dose group (5/26); there were 2/21 deaths in the mid-dose group. Clinical signs (piloerection) occurred in all treated groups in a dose-dependent manner. Maternal body weight gain and feed consumption were significantly reduced in the high-dose dams, but not at the lower doses. The necropsy findings showed evidence of stomach irritation in almost all of the animals that died during the study and in 12/21 of the surviving dams in the high-dose group. The number of implantations per litter, resorptions and dead foetuses per litter, live foetuses per litter and incidence of post-implantation loss per litter was similar across all groups. The mean foetal body weights for male and female foetuses were significantly reduced in the high-dose group; this was attributed to the reduced food consumption of the dams during gestation rather than a direct effect of treatment. There was no evidence of a treatment-related teratogenic effect. The NOAEL for maternal and developmental toxicity is 50 mg/kg/day, respectively (Ema et al., 1992) [Kl. score = 2].

Pregnant Himalayan rabbits were dosed by oral gavage with 0, 5, 15 or 45 mg/kg glutaraldehyde on GD 7 to 19. In the high-dose group, 5/15 died on GD 9-11. Food consumption and body weight gain were also significantly reduced in the high-dose group. Clinical observations in 12/15 high-dose does included soft faces, diarrhoea and blood in the bedding. The mean gravid uterus weight was significantly reduced in the high-dose group. Post-implantation loss was greatly increased (94.3%) in the high-dose group: no viable foetuses in 9/15 of the high-dose does, only early resorptions; only one female gave four alive foetuses on the scheduled date. There were reduced placental and foetal body weights in the only four foetuses. No significant maternal or developmental effects were seen in the mid- and low-dose groups. The NOAEL for maternal and developmental toxicity in this study is 15 mg/kg/day (ECHA) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for glutaraldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

The lowest NOAEL values from key toxicity studies on glutaraldehyde are listed in Table 6.

Table 6: Lowest NOAEL Values from Key Toxicity Studies on Glutaraldehyde by the Oral Route

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, female	90/days	4	Decreased body weights, food and water consumption	ECHA
Rats, male	13-wk (drinking water)	5	Increased kidney weights	ECHA

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, male	12-months (drinking water)	30.5	Clinical signs; decreased body weights and food consumption; increased clear cell foci in liver	ECHA
Rats, male	2-yr (drinking water)	4	Reduced body weight, body-weight gain, and food consumption	Van Miller *et al.* (2002)
Rats	2-generation (drinking water)	58	Systemic toxicity	ECHA
Rats	GD 6-16 (drinking water)	68	Developmental toxicity	ECHA
Rats	GD 6-15 (oral gavage)	50	Developmental toxicity	Ema *et al.* (1992)
Rabbits	GD 7-19 (oral gavage)	15	Developmental toxicity	ECHA

The lowest NOAEL from these studies is 4 mg/kg/day based on reduced body weights, body weight gain and feed consumption in male rats from the two-year drinking water study (Van Miller et al., 2002). The NOAEL of 4 mg/kg/day will be used for determining the oral Reference Dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4/(10 x 10 x 1 x 1 x 1) = 4/100 = <u>0.04 mg/kg/day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD: Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2 L (ADWG, 2011)
Drinking water guidance value = (0.04 x 70 x 0.1)/2 = 0.14 mg/L

B. Cancer

Increased incidence of large granular cell lymphatic leukaemia (LGLL) was observed in all groups of male and female Fischer 344 rats given glutaraldehyde in their drinking water, including the controls (Van Miller *et al.,* 2002). For the males, the incidence of LGLL was not statistically significantly increased. However, for the females, the incidence of LGLL was significantly increased in all treated females (≥ 50 ppm). Inhalation exposure of Fischer 344 rats to glutaraldehyde did not result in an increased incidence of tumours, including LGLL.

LGLL, also known as mononuclear cell leukaemia, is an extremely common spontaneous neoplastic disease of the ageing F344 rat (Stromberg, 1985; Ward *et al.* 1990; Thomas et al., 2007). Consistent features are splenomegaly, anaemia, thrombocytopenia and leukemic infiltration of the spleen, liver, lung, and in an advanced stage, of several other organs. The incidence is variable but has been increasing progressively with time and can exceed 70% in controls in some studies. This compares with background incidence of less than 1% in other strains of commonly used laboratory rats (Haseman et al., 1998; Thomas et al., 2007). The incidence in F344 rats is modulated by a variety of factors not clearly related to carcinogenicity. Corn oil gavage, for example, has been shown consistently to reduce the incidence of MCL in male, but not female, controls (reviewed in Thomas et al., 2007).

The neoplastic mononuclear cells appear to be derived from large granular lymphocytes (LULs) (reviewed in Thomas et al., 2007). The tumour cell is of the NK type in most, if not all, cases. LGL leukaemia, although uncommon, does occur in humans. There are two types: T-LGL leukaemia which has a chronic course characterised by neutropenia, recurrent infections, splenomegaly and accompanying rheumatoid arthritis, and the much rarer NK-LGL leukaemia which has an acute course, more pronounced splenomegaly, and thrombocytopenia. The latter type appears to resemble more closely the disease in the F344 rat than the former. The aetiology of human LGL leukaemia is unknown. There is some evidence that viral infection may play a role but no evidence that a chemically-related increased of LGLL in the F344 rat is indicative of the potential to induce LGL leukaemia in humans.

To extrapolate results from an animal model that has a clear predisposition (high spontaneous rates) to a tumour type to humans, of which this is not the case, seems inappropriate if the mechanism(s) for LGLL formation in that strain is not understood. Although that rat strain may be useful for understanding the disease process in humans, it does not seem reasonable to use the results from that rat strain for risk assessment purposes. There should be confirmation of a putative leukemogenic effect in the F344 rat in another strain before any conclusions are made about the use of this tumour type for human health risk assessment purposes.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Glutaraldehyde does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has a moderate acute toxicity concern to fish and invertebrates, but is highly toxic to algae. It is of low toxicity concern to terrestrial invertebrates and plants. To birds, glutaraldehyde is moderately toxic on an acute basis and slightly toxic on a subacute dietary basis.

B. Aquatic Toxicity

Acute Studies

Table 7 lists the results of acute aquatic toxicity studies conducted on glutaraldehyde.

Table 7: Acute Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill sunfish	96-hr LC_{50}	13	2	ECHA
Oncorhynchus mykiss	96-hr LC_{50}	10	2	ECHA
Daphnia magna	48-hr LC_{50}	14.87	2	ECHA
Daphnia magna	48-hr LC_{50}	14	2	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.375 (biomass) 0.6 (growth rate) 0.025 (NOEC)	1	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.92 (growth rate) 0.61(biomass) 0.33 (NOEC)	2	ECHA; Leung, 2001
Scenedesmus subspicatus	72-hr EC_{50}	0.61 (growth rate)	2	ECHA

Chronic Studies

The chronic aquatic toxicity studies conducted on glutaraldehyde are listed in Table 8.

Table 8: Chronic Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Kl. score	Reference
Oncorhynchus mykiss	97/day (OECD 210)	LOEC = 5 NOEC = 1.6	1	ECHA
Daphnia magna	21/day	NOEC = 5	1	ECHA

C. Terrestrial Toxicity

Table 9 lists the results of toxicity studies conducted on glutaraldehyde with earthworms, soil microorganisms and birds.

Table 9: Terrestrial Toxicity Studies on Glutaraldehyde

Test Species (method)	Endpoint	Results	Kl. score	Reference
Earthworm *Eisenia fetida* (OECD 207)	14-d LC_{50}	> 500 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 216)	28-d EC_{50} 28-d EC_{10}	360 mg/kg soil dw 11.5 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 217)	28-d EC_{50} 28-d EC_{10}	> 593 mg/kg soil dw 1.5 mg/kg soil dw	1	ECHA
Mallard ducks	Single-dose (oral gavage) LC_{50}	206 mg/kg	2	ECHA
Mallard ducks	5-d (dietary) NOEC	> 2,500 ppm	1	ECHA

*organic carbon content of soil = 1.34% dry weight

Glutaraldehyde has also been evaluated in a terrestrial plants test: seedling emergence and seedling growth test (OECD TG 208). The test material contained 48.9% glutaraldehyde. The results are as follows:

Avena sativa (oats): 19/day EC_{50} value is > 1,000 mg/kg soil dry weight based on emergence rate, dry weight and shoot length. The NOECs for *Avena sativa* (oats) were $\geq$ 1,000 mg/kg dry weight on all three parameters tested.

Brassica napus (rapeseed): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length and 994 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 500 and 250 mg/kg soil dry weight for emergence rate, dry matter and shoot length, respectively.

Vicia sativa (vetch): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length, and 901 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 125 and 125 mg/kg soil dry weight for emergence rate, dry matter, and shoot length, respectively (ECHA) [Kl. score = 1].

D. Calculation of PNEC

The PNEC calculations for glutaraldehyde follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (10 mg/L), *Daphnia* (14 mg/L) and algae (0.375 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 0.025 mg/L for algae. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 0.025 mg/L for algae. The $PNEC_{water}$ is 0.0025 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.006 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (3.1/1280) \times 1000 \times 0.0025$
$= 0.006$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 4.8)/1000 \times 2400]$
$= 3.1\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{0c} \times f_{oc}$
$= 120 \times 0.04$
$= 4.8$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for glutaraldehyde in sediment is 120.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil

Experimental results are available for three trophic level. An acute LC_{50} value is available for earthworms (> 500 mg/kg). Results from long-term studies are available for two trophic levels, with the lowest NOEC or EC_{10} being 1.5 mg/kg soil dry weight for soil organisms.

The EC_{10} value is corrected for bioavailability of glutaraldehyde in soil by normalising to the fraction organic carbon matter content (Fom) in the soil using the following equation:

$EC_{10(std)} = EC_{10(exp)} \times Fom_{soil(std)}/Fom_{soil(exp)}$

Where:
$Fom_{soil(std)}$ = 1% (default soil fraction organic matter)
$Fom_{soil(exp)}$ = 1.34% (see Table 9)
$EC_{10(std)}$ = 1.5 mg/kg x 1/1.34 = 1.12 mg/kg

On the basis that the data consists of one short-term result from one trophic level and two long-term results from two additional levels, an assessment factor of 50 has been applied to the lowest reported long-term EC_{10} of 1.12 mg/kg soil dry weight [corrected for organic carbon content] for soil organisms. The $PNEC_{soil}$ is 0.02 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Glutaraldehyde is readily biodegradable and thus does not meet the screening criteria for persistence.

The log K_{ow} for glutaraldehyde at different pH values ranges from -0.36 to -0.80. Thus, glutaraldehyde does not meet the screening criteria for bioaccumulation.

The lowest NOEC value from chronic aquatic toxicity studies is < 0.1 mg/L. Thus, glutaraldehyde meets the screening criteria for toxicity.

The overall conclusion is that glutaraldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 3 [oral]

Acute Toxicity Category 2 [inhalation]

Skin Corrosion Category 1B

Eye Damage Category 1

Respiratory Sensitiser 1A

Skin Sensitiser 1A

STOT Single Exposure Category 3 [respiratory irritation]

Aquatic Acute Category 1

Aquatic Chronic Category 2

The appropriate hazard statements corresponding the GHS classifications are to be added to the SDS, including the non-GHS hazard statement “AUH071: Corrosive to the Respiratory Tract”.

B. Labelling

Danger

C. Pictograms



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

First aid information was obtained from the ECHA REACH database (ECHA).

Eye Contact

Wash immediately and continuously with flowing water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist. Eye wash fountain should be located in immediate work area.

Skin Contact

Take off contaminated clothing. Wash skin with soap and plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice. Wash clothing before reuse. Shoes and other leather items which cannot be decontaminated should be disposed of properly. Safety shower should be located in immediate work area.

Inhalation

Move person to fresh air. If a person is not breathing, call an emergency responder or ambulance, then give artificial respiration; if by mouth-to-mouth use rescuer protection (pocket mask, etc.). Call a poison control centre or doctor for treatment advice. If breathing is difficult, oxygen should be administered by qualified personnel.

Ingestion

If the person is fully alert and cooperative, have the person rinse mouth with plenty of water. In cases of ingestion have the person drink 4 to 10 ounces (120-300 mL) of water. Do not induce vomiting. Do not attempt mouth rinse if the person has respiratory distress, altered mental status, or nausea and vomiting. Call a physician and/or transport to an emergency facility immediately. See Note to Physician. Seek medical attention immediately.

Notes to Physician

Maintain adequate ventilation and oxygenation of the patient. May cause asthma-like (reactive airways) symptoms. Bronchodilators, expectorants, antitussives and corticosteroids may be of help. Glutaraldehyde may transiently worsen reversible airways obstruction including asthma or reactive airways disease. Chemical eye burns may require extended irrigation. Obtain prompt consultation, preferably from an ophthalmologist. If the burn is present, treat as any thermal burn, after decontamination. Due to irritant properties, swallowing may result in burns/ulceration of mouth,

stomach and lower gastrointestinal tract with subsequent stricture. Aspiration of vomitus may cause lung injury. Suggest endotracheal/oesophagal control if lavage is done. Probable mucosal damage may contraindicate the use of gastric lavage. Inhalation of vapours may result in skin sensitisation. In sensitised individuals, re-exposure to very small amounts of vapour, mist or liquid may cause a severe allergic skin reaction. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Have the Safety Data Sheet, and if available, the product container or label with you when calling a poison control centre or doctor, or going for treatment.

Medical Conditions Aggravated by Exposure

Excessive exposure may aggravate pre-existing asthma and other respiratory disorders (e.g., emphysema, bronchitis, reactive airways dysfunction syndrome).

Emergency Personnel Protection

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). If the potential for exposure exists, refer to Section 8 of the Safety Data Sheet for specific personal protective equipment.

B. Fire Fighting Information

Firefighting information was obtained from the ECHA REACH database (ECHA).

Extinguishing Media

Use water fog, carbon dioxide, dry chemical or foam to extinguish combustible residues of this product

Specific Exposure Hazards

This material will not burn until the water has evaporated. Residue can burn. Some components of this product may decompose under fire conditions. The smoke may contain unidentified toxic and/or irritating compounds. Combustion products may include, and are not limited to, carbon monoxide and carbon dioxide.

Special Protective Equipment for Firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots and gloves). Avoid contact with this material during firefighting operations. If contact is likely, change to full chemical resistant firefighting clothing with self-contained breathing apparatus. If this is not available, wear full chemical resistant clothing with self-contained breathing apparatus and fight the fire from a remote location.

C. Accidental Release Measures

Information on accidental release measures was obtained from the ECHA REACH database (ECHA).

Personal Precautions

Use appropriate safety equipment. Evacuate area. Keep upwind of the spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations.

Environmental Precautions

Spills or discharge to natural waterways is likely to kill aquatic organisms. Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Steps to be Taken if Material is Released or Spilt

Avoid making contact with spilt material; glutaraldehyde will be absorbed by most shoes. Always wear the correct protective equipment, consisting of splash-proof mono-goggles, or both safety glasses with side shields and a wraparound full-face shield, appropriate gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilt material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilt material with water to reduce odour, and discharge the rinsate into a municipal or industrial sewer.

Large spills: In the case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious to glutaraldehyde, including rubber boots or shoe protection. Deactivate with sodium bisulphite (2-3 parts [by weight] per part of active substance glutaraldehyde), collect the neutralised liquid and place in a drum for transit to an approved disposal site.

D. Storage and Handling

Information on storage and handling was obtained from the ECHA REACH database (ECHA).

General Handling

Do not get in eyes, on skin, on clothing. Avoid breathing vapour. Do not swallow. Keep container closed. Use with adequate ventilation. Wear goggles, protective clothing and butyl or nitrile gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Other Handling Precautions

Do not spray or aerosolise the undiluted form of the product. Full personal protective equipment (including skin covering and full-face SCBA respirator) is required for dilutions or mixtures of the product used in a spray application.

Storage

Do not store in: Aluminium. Carbon steel. Copper. Mild steel. Iron. Shelf life: Use within 12 Months.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for glutaraldehyde in Australia is 0.1 ppm (0.41 mg/m^3) as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

The information below on exposure controls and personal protection was obtained from the Halliburton Safety Data Sheet (SDS) on ALDACIDE® G ANTIMICROBIAL (revision date: 11-Dec-2014).

Engineering Controls

Use in a well-ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation. If vapours are strong enough to be irritating to the nose or eyes, the TLV is probably being exceeded, and special ventilation or respiratory protection may be required.

Personal Protection Equipment

Respiratory Protection: If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH-certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Full Facepiece Respirator with Organic vapour cartridge with particulate pre-filter.

Hand Protection: Chemical-resistant protective gloves (EN 374). Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480-minute permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness). This information is based on literature references and on information provided by glove manufacturers or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g., temperature). If signs of wear and tear are noticed, then the gloves should be replaced. Manufacturer's directions for use should be observed because of the great diversity of types.

Skin Protection: Butyl coated apron or clothing.

Eye protection: Splash proof chemical mono-goggles or safety glasses with side shield in conjunction with a face shield. Do NOT wear contact lenses.

Other Precautions: Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

For aqueous glutaraldehyde solutions at a concentration that is corrosive (i.e., 30% and higher):

Australia Dangerous Goods

UN3265, Corrosive Liquid, Acidic, Organic, N.O.S. (Contains Glutaraldehyde)

Class 8

Packing Group III

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII.REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ema, M., Itami, T., and Kawasaki, H. (1992). Teratological assessment of glutaraldehyde in rats by gastric intubation. Toxicol. Lett. 63: 147-153.

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Frantz, S.W., Beskitt, J.L., Tallant, M.J., Futrell, J.W., and Ballantyne, B. (1993). Glutaraldehyde: species comparisons of in vitro skin penetrations. J. Toxicol.-Cut. & Ocular Toxicol. 12: 349-361.

Gross, E.A., Mellick, P.W., Kari, F.W., Miller, F.J., and Morgan, K.T. (1994). Histopathology and cell replication responses in the respiratory tract of rats and mice exposed by inhalation to glutaraldehyde for up to 13 weeks. Fundam. Appl. Toxicol. 23: 348-362.

Haseman, J.K., Hailey, J.R., and Morris, R.W. (1998). Spontaneous neoplasm incidences in Fischer 344 rats and B6C3F_1 mice in two-year carcinogenicity studies: A National Toxicology Program update. Toxicol. Pathol. 26: 428-441.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Leung, H.W. (2001). Ecotoxicology of glutaraldehyde: review of environmental fate and effects studies. Ecotoxicol. Environ. Safety 49: 26-39.

Mirsalis, J.S., Tyson, C.K., Steinmetz, K.L., Loh, E.K., Hamilton, C.M., Bakke, J.P., and Spalding, J.W. (1989). Measurement of unscheduled DNA synthesis and S-phase synthesis in rodent hepatocytes following in vivo treatment: testing of 24 compounds. Environ. Mol. Mutagen. 14: 155-164.

Neeper-Bradley, T.L., and Ballantyne, B. (2000). Two-generation reproduction study by dosing with glutaraldehyde in the drinking water of CD rats. J. Toxicol. Environ. Health A 61: 107-129.

NICNAS. (1994). Glutaraldehyde – Full Public Report. National Industrial Chemicals Notification and Assessment Scheme (NICNAS), AGPS, Canberra, Australia.

OECD. (1995). OECD-SIDS document on Glutaraldehyde, CAS No. 111-30-8, UNEP Publications. Accessed at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=b13f2e48-0425-4a8a-b7b8-c04cfaab06e8

Stromberg, P.C. (1985). Large granular lymphocyte leukaemia in F344 rats: Model for human T lymphoma, a malignant histiocytosis and T-cell chronic lymphocytic leukaemia. Am. J. Pathol. 119: 517-519.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P.J. (2007). A review of large granular lymphocytic leukaemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

van Birgelen, A.P.J.M., Chou, B.J., Renne, R.A., Grumbein, S.L., Roycroft, J.H., Hailey, J.R., and Bucher, J.R. (2000). Effects of glutaraldehyde in a 2-year inhalation study in rats and mice. Toxicol. Sci. 55: 195-205.

Van Miller, J.P., Hermansky, S.J., Losco, P.E., and Ballantyne, B. (2002). Chronic toxicity and oncogenicity study with glutaraldehyde dosed in the drinking water of Fischer 344 rats. Toxicol. 175: 177-189.

Vergnes, J.S., and Ballantyne, B. (2002). Genetic toxicology studies with glutaraldehyde. J. Appl. Toxicol. 22: 45-60.

Ward, J.M., Rehm, S., and Reynolds, C.W. (1990). Tumours of the haematopoietic system. In: Pathology of Tumours in Laboratory Animals, Vol. 1, Second Edition (Turusov, V.S., and Mohr, U., Eds.), pp. 625-657, International Agency for Research on Cancer, Lyon, France.

Zissu, D., Bonnet, P., and Binet, S. (1998). Histopathological study in B6C3F1 mice chronically exposed by inhalation to glutaraldehyde. Toxicol. Lett. 95: 131-139.

HYDROCHLORIC ACID

This dossier on hydrochloric acid presents the most critical studies pertinent to the risk assessment of hydrochloric acid in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from OECD-SIDS documents (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Chlorane

CAS RN: 7647-01-0

Molecular formula: HCl

Molecular weight: 36.46 g/mol

Synonyms: Hydrochloric acid; HCl; chlorane; hydrogen chloride; muriatic acid; chlorohydric acid

SMILES: Cl

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Hydrochloric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless to slightly yellow gas of fuming liquid with pungent, irritating odour.	2	ECHA
Melting Point	-114.22°C	2	ECHA
Boiling Point	-85°C	4	ECHA
Density	1.639 kg/m^3 @ 0°C (gas) 1190 kg/m^3 @ 15°C (liquid)	4	ECHA
Vapour Pressure	4,104 kPa 4,723 kPa @ 25°C	4	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble	4	ECHA
Viscosity	1.7 x 10^{-6} m^2s @ 20°C	1	ECHA

Hydrochloric acid can exist in a gaseous phase at room temperature and pressure. Hydrochloric acid is also very soluble in water and is a strong acid that dissociates completely in water to hydrogen (H^+) and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility, hydrochloric acid will be found predominantly in the aquatic environment where it dissociates completely to hydrogen (H^+) and chloride (Cl^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of hydrochloric acid to an aquatic ecosystem may decrease the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of hydrochloric acid into the aquatic environment from the use of HCl could potentially increase the chloride concentration and decrease the pH in the aquatic environment. Table 2 shows the amount of hydrochloric acid that would need to be added to bicarbonate solutions to obtain pH values of 6.0 and 4.0. The UNEP (1995) study reported that the 10th percentile, mean and the 90th percentile of bicarbonate concentrations in 77 rivers in North America, South America, Asia, Africa, Europe and Oceania were 20, 106, and 195 mg/L, respectively. The data show that the decrease in pH depends on the buffer capacity (bicarbonate concentration) of the receiving water. The calculated values in Table 2 were confirmed experimentally.

Table 2: Buffer capacity to maintain the pH based on bicarbonate concentration from UNEP monitoring data (de Groot and van Dijk, 2002; taken from OECD, 2002b)

Initial concentration of HCO_3^-	Final pH	Concentration of HCl required to obtain the final pH value
		Calculated (mg/L)
20 mg/L HCO_3^- (10th percentile 77 rivers)	6.0	8.28
	4.0	11.9
106 mg/L HCO_3^- (mean value of 77 rivers)	6.0	43.9
	4.0	63.2
195 mg/L HCO_3^- (90th percentile 77 rivers)	6.0	80.7
	4.0	116.3

H^+ and Cl^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002a,b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Hydrochloric acid is a corrosive liquid. Depending on the concentration, aqueous solutions of hydrochloric acid (HCl) are either corrosive, irritating or non-irritating to the skin, eyes and gastrointestinal tract. Vapours from aqueous solutions of HCl can cause respiratory irritation. HCl is not a skin sensitiser. Subchronic inhalation studies show localised irritation to the upper respiratory tract of rats and mice, but no systemic toxicity. No repeated dose toxicity studies have been conducted by the oral route. Positive findings have been reported in some *in vitro* genotoxicity studies, which are considered to be the result of the pH change in the test system. A lifetime inhalation study showed no carcinogenicity in rats exposed to HCl. No adequate reproductive or developmental studies have been conducted on HCl.

B. Acute Toxicity

The oral LD_{50} values in rats were reported to be 238 to 277 mg/kg and 700 mg/kg (OECD, 2002a,b) [Kl. scores = 2 and 4, respectively].

The lethal dose by dermal exposure is > 5,010 mg/kg for rabbits (OECD 2002a,b) [Kl. score = 4].

The LC_{50} values in rats for HCl gas are 40,989 and 4,701 ppm for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2]. The LC_{50} values in rats for HCl aerosol are 31,008 and 5,666 ppm (45.6 and 8.3 mg/L) for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2].

C. Irritation

Application of a 37% aqueous solution of HCl for 1 or 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 2]. Application of 0.5 mL of a 17% solution of aqueous solution of HCl for 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 3]. Moderate skin irritation was observed in rabbits following an application of 0.5 mL of a 3.3% aqueous solution of HCl for five days; no irritation was observed with 0.5 mL of a 1% aqueous solution (OECD, 2002a,b) [Kl. score = 2]. In humans, an aqueous solution of 4% of HCl was slightly irritating, while a 10% solution was sufficiently irritating to be classified as a skin irritant (OECD, 2002a,b).

Instillation of 0.1 mL of a 10% aqueous solution of HCl to the eyes of rabbits resulted in severe eye irritation (ECHA) [Kl. score = 2]. Instillation of 0.1 mL of a 5% solution of HCl produced corneal opacity, iridial lesions, conjunctival redness and chemosis in 3/3 animals at 1 hour and at day one post-instillation. There was no recovery in any animal and the study was terminated on day two (ECHA) [Kl. score = 1].

D. Sensitisation

Hydrochloric acid was not a skin sensitiser in a guinea pig maximisation test (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

No adequate studies were located.

Inhalation

Male and female SD rats and F344 rats were exposed by inhalation to 0, 10, 20, or 50 ppm 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm male F344 rats. There were no treatment-related effects on the haematology or clinical chemistry parameters or urinalysis. At study termination, heart, kidney and testes weights were increased in the 100 and/or 50 ppm groups; these changes were considered to be mainly related to the treatment-related effect on body weight. Histopathological examination showed minimal to mild rhinitis in the ≥ 20 ppm dose groups of both strains of rats (both sexes). The NOAELs for systemic toxicity and localised irritation (site-of-contact) are 20 and 10 ppm, respectively (ECHA) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 10, 20 or 50 ppm HCl, 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm groups. At study termination, absolute liver weights were decreased in the 50 ppm males. Histopathologic examination showed only eosinophilic globules in the nasal epithelium in the 50 ppm animals. The NOAEL for this study is 20 ppm (ECHA) [Kl. score = 1].

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium (ECHA) [Kl. score = 2].

Dermal

No studies were located.

F. Genotoxicity

In Vitro Studies

Table 3 presents the *in vitro* genotoxicity studies on hydrochloric acid.

Table 3: *In Vitro* Genotoxicity Studies on Hydrochloric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	+	2	ECHA
Chromosomal aberration (CHO cells)	+	+	2	ECHA
Saccharomyces cerevisiae (mitotic recombination	-	-	2	ECHA
E. coli W3110 (pol A+) and P3078 (pol A-) repair assay	-	-	2	ECHA

* +, positive; -, negative

In the mouse lymphoma assay, the mutant frequency increased as the pH was lowered to 6.5 to 6.0 (from increased HCl) in the presence of metabolic activation. A decrease in pH from the addition of HCl to the medium also resulted in clastogenic effects to CHO cells in the absence or presence of metabolic activation. The positive findings in these two studies are considered to be the result of the pH change in the test media.

In Vivo Studies

No adequate studies were located.

G. Carcinogenicity

Oral

No studies were located.

Inhalation

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium. There was no increased incidence of tumours in the HCl-treated rats compared to controls (ECHA) [Kl. score = 2].

H. Reproductive Toxicity

No studies were located.

I. Developmental Toxicity

No adequate studies were located.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Repeated dose, reproductive and developmental toxicity studies by the oral route have not been conducted on hydrochloric acid. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of hydrochloric acid, which would limit the amount of absorbed HCl. Hydrochloric acid dissociates to hydrogen and chloride ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, an oral toxicological reference and drinking water guidance values were not derived from hydrochloric acid.

The Australian drinking water guideline values for pH (6.5 to 8.5) and chloride (250 ppm, aesthetics) may be applicable (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Hydrochloric acid does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The hazard of hydrochloric acid for aquatic organisms is caused by the hydrogen ion (H^+). The toxicity values in terms of mg/L are not relevant because of the varying buffering capacity of different test systems and different aquatic ecosystems.

B. Aquatic Toxicity

Acute Studies

The acute aquatic toxicity studies on hydrochloric acid are listed in Table 4.

Table 4: Acute Aquatic Toxicity Studies on Hydrochloric Acid

Test Species	Endpoint	Results	Klimisch score	Reference
Lepomis macrochirus	96-hour LC_{50}	pH 3.25 – 3.5 (20 mg/L)	2	ECHA; OECD 2002a,b
Daphnia magna	48-hour EC_{50}	pH 4.92 (0.45 mg/L)	1	ECHA
Chlorella vulgaris	72-hour EC_{50} 72-hour EC_{10}	pH 4.7 [growth rate] (0.73 mg/L) PH 4.7 (0.364 mg/L)	1	ECHA

Chronic Studies

No chronic studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

PNEC values were not derived from hydrochloric acid because factors such as the buffer capacity, the natural pH and the fluctuation of the pH are very specific for a certain ecosystem.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Hydrochloric acid is an inorganic salt that dissociates completely to hydrogen and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both hydrogen and chloride ions are also ubiquitous and are present in water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Hydrogen and chloride ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, hydrochloric acid is not expected to bioaccumulate.

No chronic toxicity data exist on hydrochloric acid. The acute EC_{50} values are > 1 mg/L in fish, < 1 mg/L for invertebrates and algae. Thus, hydrochloric acid meets the screening criteria for toxicity.

The overall conclusion is that hydrochloric acid is a PBT substance based on toxicity to invertebrates and algae.

IX. CLASSIFICATION AND LABELLING

A. Classification

For HCl concentrations of >25%:

- Metal Corrosive Category 1
- Skin Corrosive 1B
- STOT SE Category 3 [Respiratory irritant]

In addition to the hazard statements corresponding to the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

According to the classification provided by companies to ECHA in REACH registrations this substance causes severe skin burns and eye damage, is toxic if inhaled, may damage fertility or the unborn child, causes serious eye damage, may cause damage to organs through prolonged or repeated exposure, may be corrosive to metals and may cause respiratory irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

<u>Skin Contact</u>

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of the body with soap and fresh water. Get medical attention immediately.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device. Give artificial respiration if the victim is not breathing. Get medical attention immediately.

Ingestion

Rinse mouth and lips with plenty of water if a person is conscious. Do not induce vomiting. Do not use mouth-to-mouth method if the victim ingested the substance. Obtain medical attention immediately if ingested.

Notes to Physician

Treat as corrosive due to pH of the material. All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use dry chemical, carbon dioxide, water spray or fog, or foam.

Specific Exposure Hazards

Containers may explode when heated. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following materials: halogenated compounds, may release dangerous gases (chlorine).

Special Protective Equipment for Firefighters

Structural firefighter's protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible. Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Wear positive pressure self-contained breathing apparatus (SCBA). Move containers from the fire area if you can do it without risk.

C. Accidental Release Measures

Personal Precautions

Ventilate enclosed areas. Do not walk through spilt material. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours, or spray. Do not get in eyes, on skin, or on clothing.

Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

Steps to be Taken if Material is Released or Spilt

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). As an immediate precautionary measure, isolate spill or leak area for at least 50 meters in all directions. Keep unauthorised personnel away. Stay upwind. Keep out of low areas. Do not get water inside container.

D. Storage and Handling

General Handling

Handle and open container with care. Use only with adequate ventilation. Keep away from heat. Use caution when combining with water. DO NOT add water to corrosive liquid, ALWAYS add corrosive liquid to water while stirring to prevent the release of heat, steam and fumes. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours or spray. Do not get in eyes, on skin or on clothing. Do not ingest. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

Storage

Keep contain tightly closed. Store in a cool, dry, well-ventilated place. Keep away from incompatible materials. Keep from direct sunlight. Separate from alkalis. Do not store above 49°C/120°F.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for hydrochloric acid in Australia is 5 ppm (7.5 mg/m^3 as a peak limitation, with a sensitisation notation). A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection is based on known or anticipated exposure levels, the hazard of the product and the safe working limits of the selected respirator.

Hand Protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for

any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Skin Protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling hydrochloric acid.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Australian Dangerous Goods

UN 1789 (HYDROCHLORIC ACID)

Class: 8

Packing Group: II or III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

de Groot, W.A., and van Dijk, N.R.M. (2002). Addition of hydrochloric acid to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals, Study No. A SOL.S.027; cited in OECD 2002a,b.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2002a). IUCLID Data Set for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

SODIUM CHLORIDE

This dossier on sodium chloride presents the most critical studies pertinent to the risk assessment of sodium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): sodium; chloride

CAS RN: 7647-14-5

Molecular formula: NaCl

Molecular weight: 58.44 g/mol

Synonyms: Halite, Salt, Table salt, Saline, Rock salt, Common salt, Dendritis, Purex'

SMILES: [Cl-].[Cl-].[Ca+2]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystaline solid	-	ECHA
Melting Point	801 °C @ 101.3 kPa	-	ECHA
Boiling Point	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Density	2163 kg/m^3 @ 20 °C	1	ECHA
Vapour Pressure	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Partition Coefficient (log K_{ow})	The study does not need to be conducted, because NaCl is inorganic.	1	ECHA
Water Solubility	317 g/L @ 20°C	2	ECHA
Dissociation Constant (pKa)	Not applicable, NaCl is an electrovalent substance.	-	ECHA

III. ENVIRONMENTAL FATE SUMMARY

Sodium chloride (NaCl) dissociates completely in aqueous solutions to sodium (Na^+) and chloride (Cl^-) ions. Sodium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of sodium (Na^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH, and organic matter. Similar to potassium, sodium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (DoEE, 2017; OECD, 2001).

Chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001). Neither sodium chloride nor its dissociated ions are expected to bioaccumulate.

Release to surface waters under the assessed circumstances is expected to have limited long-term environmental effects as these salts are ubiquitous and are present in most water, soil and sediment, therefore organisms are adapted to a level of exposure. The magnitude of the acute effect for a receiving aquatic environment would depend on the released concentrations as well as the degree of adaptation of species present to these naturally occurring ions and salts (DoEE, 2017).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Historically, sodium chloride (as a major ingredient in edible salt) has been commonly used in cooking as a condiment and food preservative. Sodium is an electrolyte that regulates the amount of water in your body and also plays a part in nerve impulses and muscle contractions. When depleted in the body, sodium must be replaced in order to maintain intracellular osmolarity, nerve condition, muscle contraction and normal renal function. Sodium chloride is used to treat or prevent sodium loss caused by dehydration, excessive sweating or other causes.

The NHMRC has established dietary guidelines for the intake of sodium per day (adult) as less than 2,000 mg sodium per day (NHMRC, 2007 updated 2017). Sodium chloride is categorised under GRAS (Generally Recognised as Safe) by the FDA (U.S. Food and Drug Administration) and the average daily levels of sodium intake for adults range from 2 to 5 grams. A technical report by WHO and the Food and Agriculture Organization (FAO) recommended the consumption of less than 5 grams sodium chloride (or 2 grams sodium) per day as a population nutrient intake goal, while ensuring that the salt is iodised (WHO, 2007).

NICNAS has assessed sodium chloride in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health or the environment[1] .

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 7647-14-5

Sodium chloride has low acute toxicity by the oral, dermal or inhalation route. It is not a skin irritant or a skin sensitiser. Long-term studies in rats fed sodium chloride showed elevated blood pressure. It is not a carcinogen and nor a developmental toxicant.

B. Acute Toxicity

Oral

The acute oral LD_{50} values of sodium chloride in rats is greater than 3,550 mg/kg with fiducial limits of 3,040 – 4,140 mg/kg (ECHA) [KI scores = 2].

Dermal

A dermal toxicity study was conducted in rabbits and the LD_{50} value was greater than 10,000 mg/kg and hence not classified according to EU Annex VI (ECHA) [KI scores = 2].

Inhalation

An acute inhalation toxicity study was conducted at a dose of 42 mg/L administered as an aerosol of a 20% aqueous solution to male rats and the results of the study indicated that the LC_{50} of sodium chloride was greater than 42 mg/L (42,000 mg/m^3) and hence not classified (ECHA) [KI scores = 2].

C. Irritation

Skin

When in contact with the intact skin, sodium chloride causes no response, either in undiluted form or in solution. Sodium chloride is considered to be slightly to not irritating to the skin (ECHA) [KI score = 2].

Eye

No adequate or reliable studies are available.

D. Sensitisation

Sodium chloride is not considered to be a skin sensitiser (ECHA).

E. Repeated Dose Toxicity

Oral

The estimated fatal dose of sodium chloride is approximately 0.75 to 3.00 g/kg (HSDB - Hazard Substance Data Bank - 750 to 3000 mg/kg). The lowest toxic dose (TDLo) for an adult man with normal blood pressure is 8,200 mg/kg (Patty's Handbook of Toxicology). High oral sodium chloride intake is associated with increased risk of hypertension; however, this is a well studied field in humans and additional animal testing data would not add value. Based on the studies, sodium chloride is not classified for any repeated dose effects.

A two-year feeding study was conducted to investigate the impact of sodium chloride on rats. Animals received a chronic administration at doses of 4% sodium chloride over a period

of 2 years which induces elevated blood pressure in the rats. The LOAEL from this key study identified a dose level of < 4% via the diet and the calculated LOAEL was 2,533 mg/kg/day (ECHA).

Dermal

No adequate or reliable studies are available.

Inhalation

No adequate or reliable studies are available.

F. Genotoxicity

No adequate or reliable studies are available.

G. Carcinogenicity

Sodium chloride is not classified as a carcinogen (ECHA). Sodium chloride is not listed with IARC.

H. Reproductive Toxicity

No adequate or reliable studies are available.

I. Developmental Toxicity

Sodium chloride is not classified as a developmental toxicant (ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2011).

The Australian drinking water guideline value for sodium ions is 180 mg/L based on aesthetics (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Sodium chloride is of low acute toxicity concern to aquatic organisms, in part because of the effect of pH changes from the dissociated hydrogen ion.

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} value of 5,840 mg/L for sodium chloride was determined in a continuous flow-through exposure system with bluegill sunfish (*Lepomis macrochirus*) (ECHA) [KI score =1].

The EC_{50} 48-hour (immobilisation, *Daphnia magna*) was determined to be 1,900 mg/L (ECHA) [KI score = 2].

The EC_{50} of NaCl at 96 hours to *Lemna* was determined for comparison and found to be 6,870 mg/L (6.87 g/L) (ECHA) [KI score = 1].

Chronic Studies

The 33-day NOEC value of 252 mg/L for sodium chloride was determined in a continuous flow-through exposure system with early life stage fathead minnows (*Pimephales promelas*) (ECHA) [KI score = 2].

A 21-day NOEC (reproduction, *Daphnia pulex*) was determined to be 314 mg/L (ECHA) [KI score = 2].

C. Terrestrial Toxicity

The mean 14-day LC_{50} for three experiments conducted with the earthworm, *E. fetida* was 3,296 mg NaCl/kg soil dw. The 10-week NOEC (based on mortality) was 3,507 mg NaCl/kg soil for the earthworm, *E. fetida* (ECHA) [KI score = 2].

In a 7-day exposure study with red fescue grass, the EC_{50} for germination was 500.8 mg NaCl/kg soil dw. In a 7-day exposure study with Kentucky bluegrass, the NOEC for stem growth was 243 mg NaCl/kg soil dw (ECHA) [KI score = 2].

The 12-hour LD_{50} for wild house sparrows was approximately 3,000 - 3,500 mg/kg NaCl (ECHA) [KI score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium chloride is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium chloride.

Bioaccumulation in fish is not expected given the inorganic nature of the substance. Thus, sodium chloride does not meet the screening criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on sodium chloride are greater than 0.1 mg/L. The E(L)C_{50} values from the acute aquatic toxicity studies on sodium chloride are > 1 mg/L. Thus, sodium chloride, does not meet the criteria for toxicity.

The overall conclusion is that sodium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes of chloride and sodium oxide (above 1,413°C). Depending on conditions, decomposition products may include hydrogen chloride gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment and Energy [DoEE]. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report prepared by the Chemicals and Biotechnology Assessments Section (CBAS), in the Chemicals and Waste Branch of the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HSBD. Hazardous Substances Data Bank. https://pubchem.ncbi.nlm.nih.gov/source/hsdb/6368

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NHMRC. (2007). Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes, Version 1.2 updated September 2017. National Health and Medical Research Council. Department of Health and Ageing. Australian Government.

OECD. (2001). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

Patty's Toxicology, 6 Volume Set, 6th Edition. Volume 3: 375. July 2012.

WHO. (2007) Reducing salt intake in populations: report of a WHO forum and technical meeting. https://www.who.int/dietphysicalactivity/Salt_Report_VC_april07.pdf. Accessed 28 Apr 2020

DIETHYLENE GLYCOL

This dossier on diethylene glycol presents the most critical studies pertinent to the risk assessment of diethylene glycol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-(2-hydroxyethoxy)ethan-1-ol

CAS RN: 111-46-6

Molecular formula: $C_4H_{10}O_3$ or $(CH_2CH_2OH)_2O$

Molecular weight: 106.12 g/mol

Synonyms: Diethylene glycol; 2,2'-oxydiethanol; diglycol; bis(2-hydroxyethyl) ether; 2-hydroxyethyl ether; 2,2'-oxybisethanol; 2-(2-hydroxyethoxy)ethanol; ethanol, 2,2'-oxybis-; 2-(2-hydroxyethoxy)ethan-1-ol; glycol ethyl ether; ethylene diglycol

SMILES: C(COCCO)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	A colourless viscous liquid	2	ECHA
Melting point	-6.5°C @ 101.3 kPa	2	ECHA
Boiling point	244.9°C @ 101.3 kPa	2	ECHA
Density	1,118 kg/m^3 @ 20°C	2	ECHA
Vapour pressure	0.008 hPa @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	-1.98 (calculated)	2	ECHA
Water solubility	1,000 g/L @ 20°C	2	ECHA
Flash point	138°C	2	ECHA
Auto flammability	372°C	2	ECHA
Viscosity	30 mPa s (dynamic) @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is readily biodegradable, is unlikely to bioaccumulate, nor is it likely to adsorb or desorb to soil or sediment to a great extent.

B. Biodegradation

Diethylene glycol is readily biodegradable. In an OECD 301B test, there was 70-80% and 90-100% degradation after 28 days, as determined by CO_2 evolution and DOC removal respectively (ECHA) [KI score = 2].

In an OECD 301A test, there was 90-100% degradation after 28 days, although the 10-day window was missed (ECHA) [KI score = 1]. In a modified MITI I test (OECD 301C), there was up to 92% degradation after 28 days (ECHA) [KI score = 2].

C. Environmental Distribution

No experimental data are available for diethylene glycol. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} value from the molecular connectivity index (MCI) and log K_{oc} are 1 and -0.08 L/kg, respectively (ECHA) [KI Score = 2]. Based on these K_{oc} values, if released to soil, diethylene glycol is expected to not adsorb to soil and have a very high mobility. If released to water, based on the K_{oc} value and its water solubility, it is also not expected to adsorb to suspended solids and sediment.

D. Bioaccumulation

The calculated log K_{ow} for diethylene glycol is -1.98 (Verschueren, 1983). Diethylene glycol has low potential to bioaccumulate. In a 3-day bioaccumulation fish study with Leuciscus idus melanotus, the BCF was determined to be 100 (Freitag et al., 1985) [KI score = 2].

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance exhibits low oral acute toxicity. It is not a significant skin or eye irritant, nor is it considered to be a skin sensitiser. No dermal or inhalation repeat dose studies were available but oral repeat does studies suggest moderate urinary dysfunction with oxalate formation in rats. The substance is not genotoxic, carcinogenic nor developmentally toxic.

B. Acute Toxicity

The oral LD_{50} in rats is 19,600 mg/kg (Lenk et al., 1989; ECHA) [KI score = 2]; and 16,500 mg/kg (Laug et al., 1939; ECHA) [KI score = 2].

No deaths were reported in rats exposed to a saturated vapour for 6 hours (OECD, 2007) [KI score = 2]. No deaths were also reported in male and female Aplk:APfSD (Wistar-derived) rats exposed to 5,080 mg/m^3 diethylene glycol aerosol (MMAD = 2.83 µm, GSD = 2.05) for 4 hours (OECD, 2007) [KI score = 2].

The dermal LD_{50} in rabbits was reported to be 12,500 mg/kg (OECD, 2007) [KI score = 2]. The dermal LD_{50} in rabbits was reported to be 13,300 mg/kg (ECHA) [KI score = 4].

C. Irritation

When applied to the skin of rabbits for 24 hours under occlusive conditions, diethylene glycol was essentially non-irritating with a PII score of 0.04 (Guillot et al., 1982, ECHA) [KI score = 2]. In a human repeated irritation patch test, diethylene glycol was minimally irritating to the skin (OECD, 2007) [KI score = 2].

Diethylene glycol was not considered a skin irritant in an *in vitro* reconstructed human epidermis test (ECHA) [KI score = 1].

Instillation of 0.1 mL diethylene glycol into the eyes of rabbits produced minor, transient irritation; no corneal lesions were observed (OECD, 2007) [KI score = 2]. When instilled into the eyes of rabbits, the ocular irritancy was 11.67 based on a modified Kay Calandra scale of 0 to 110 (Guillot et al., 1982, ECHA) [KI score = 2].

D. Sensitisation

Diethylene glycol was not a skin sensitiser to guinea pigs in a maximisation test (OECD, 2007; ECHA) [KI score = 1]. Diethylene glycol was not a skin sensitiser in a human repeat irritation patch test (OECD, 2007; ECHA) [KI score = 4].

E. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their diet 0, 0.085, 0.17, 0.4 and 2.0% diethylene glycol for 225 days. The corresponding average daily intakes were 0, 51, 105, 234 and 1,194 mg/kg/day for males; and 0, 64, 126, 292 and 1462 mg/kg/day for females. In the 0.4% and 2% groups, there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The only finding in the 0.17% group was a 13.2% increase in urinary oxalate excretion in males; no effects were observed in the 0.085% group. The NOAEL and NOEL for this study is considered to be 0.17% (approximately 105 mg/kg/day) and 0.085% (approximately 51 mg/kg/day), respectively (ECHA) [KI score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on diethylene glycol are shown in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Diethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	OECD (2007), ECHA
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	2	OECD (2007), ECHA
Sister chromatid exchange (CHO cells)	-	-	2	OECD (2007), ECHA

*+, positive; -, negative

In Vivo Studies

Micronuclei were not increased in the bone marrow of NMRI mice given a single intraperitoneal injection of 0, 500, 1,000 or 2,000 mg/kg diethylene glycol (ECHA) [KI score = 1].

G. Carcinogenicity

Oral

Male and female F344 rats were given in their drinking water 0, 1.25 or 2.5% diethylene glycol (97% purity) for two years. The daily intake was estimated to be 0, 1,210 and 2,630 mg/kg/day for males; and 0, 1,160 and 2,550 mg/kg/day for females. Mortality was increased in the 2.5% males; drinking water consumption was increased in the 2.5% males and females. There were no significant differences in the incidence of tumours between treated and control animals (Hiasa et al., 1990; ECHA) [KI score = 2].

Male Osborne-Mendel rats were given in their feed 0, 1, 2 or 4% diethylene glycol for two years. During the first 26 weeks of the study, weight gain was significantly reduced at all dose levels. After the first year, the growth of rats fed the 4% diets was significantly reduced relative to the controls. There were no significant differences in food consumption at any treatment level. Mortality in rats fed the 4% diet was significantly higher than the control group; all animals were found dead before the end of the study (most dying during the last 12 months), compared with 7/12 control deaths. The incidence of bladder stones and bladder tumours increased with diethylene glycol exposure, with 0, 0, 6 and 5 bladder tumours observed in the control, 1, 2 and 4% DEG groups, respectively. Bladder stones were observed in 0, 2, 7 and 11 rats in the control, 1, 2 and 4% groups, respectively. In all but one case, bladder stones were present when bladder tumours were observed, suggesting that chronic irritation was a factor in the production of bladder tumours. The severity and incidence of signs of kidney damage (hydronephrosis, hydroureter, focal tubular atrophy, hyalin cast formation, glomerular atrophy) increased in a treatment-related manner, with gross kidney lesions observed in 1/12, 3/12 and 8/12 of the rats in the low-, mid- and high-dose groups, respectively. Liver damage observed histologically also increased with the level of diethylene glycol exposure. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Fitzhugh and Nelson, 1946) [KI score = 3].

Male and female rats were given in their feed 0, 2 or 4% diethylene glycol (containing 0.031% ethylene glycol) for two years. Rats were either just weaned, 2 months old or 12 months old at the initiation of the exposure. The dietary concentration of diethylene glycol was adjusted for the food consumption and body weight of each group. For 4% diet, the dosage in weanlings was 5,400 mg/kg/day for the first 28 days, approximately 3,700 mg/kg/day during the next two-week period, gradually declined to about 2,000 mg/kg/day over the next three months and remained at that level for the rest of the study. A study average of 2,300 mg/kg/day for weanlings fed 4% in the diet was calculated from data provided by the authors. None of the 12-month old male rats included in the study survived, whereas all the females in that group survived to termination of the study. Although weanling rats developed more bladder stones than the other groups, the difference was insignificant. The yearling rats developed their bladder stones somewhat earlier. The yearling rats in the 4% groups had the highest stone formation (8 out of 20 rats) and had the only bladder tumour in this dose group; the rat with the bladder tumour also had bladder stones. No bladder stones or tumours were observed in rats of any age in the control or in the 2% groups. The bladder tumours associated with the stones were considered to be the result of mechanical irritation, and diethylene glycol was not considered to be a primary rat carcinogen. The LOAEL and NOAEL for this study were dietary concentrations of 4% and 2% (approximately 2,300 and 1,200 mg/kg), respectively. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Weil et al., 1965) [Kl score = 3].

H. Reproductive Toxicity

In a two-generation study, male and female rats were dosed by oral gavage with 1 mL/100 g body weight of a 20% aqueous solution of diethylene glycol (approximately 2 mL/kg/day) for 8 weeks. A control group was given daily oral gavage doses of 1 mL/100 g body weight distilled water. Five of the treated females were dosed with diethylene glycol until parturition, the other five until the pups were weaned. Treatment of the P-generation with diethylene glycol for 12 weeks did not impair reproduction. The test animals and the controls became pregnant at almost the same time, litter size averaged 8-10 young, and the young exhibited similar, uniform development. Growth and onset of oestrus were not affected by treatment. The endocrine glands investigated showed no differences from the controls with regard to weight and fine structure. The receptiveness and litter size of the untreated F1 generation were the same as those of the P-generation, and the F2 generation was normal with regard to weight gain, onset of sexual maturity and weight as well as histology of the organs examined. The NOAEL for this study was calculated to be 2,200 mg/kg/day (Wegener, 1953; ECHA) [Kl score = 2].

A continuous breeding protocol (RACB) was used to study the reproductive toxicity of diethylene glycol in mice. Male and female CD-1 mice were administered in their drinking water 0, 0.35, 1.75 or 3.5% diethylene glycol. Mice were exposed for 7 days prior to mating, 98 days during cohabitation of breeding pairs and a further 23 days after segregation of each pair.

Breeding study: The mice given 1.75% or 3.5% diethylene glycol consumed significantly more drinking water than did the controls. On the basis of water consumption and body weight data, the 0, 0.35, 1.75 and 3.5% dose groups were equivalent to average daily intakes of 0, 612, 3,062 or 6,125 mg/kg/day, respectively. There was no treatment-related mortality. In the 3.5% dose group, there was significant decreases in the number of litters produced per pair, number of live pups per litter, proportion of pups born alive, and the absolute and adjusted pup weights. A significant dose-related trend for reduced absolute pup weights was also observed. Exposure to the 3.55 dose group also resulted in a significant increase in the cumulative days to litter and fewer breeding pairs were able

to produce litters: 82%, 76%, and 59% of the pairs exposed to 3.5% in the diet produced the third, fourth or fifth litters, respectively, whereas 97-100% of the control group produced litters.

Crossover mating: The mating index and the fertility of the 3.5% dosed males or females were unaffected compared with the control mice. However, live pup weight was decreased in the highest-dose group, in which a 9% difference was observed for the offspring of the control males and the treated females. At the end of this test the parental animals (F0 of breeding study) were necropsied. For the male mice there were no significant differences in the body or organ weights, either absolute or adjusted for body weight. Analysis of the cauda epididymal contents of F0 males at necropsy indicated that there were no effects of diethylene glycol in the highest-doses group on the sperm concentration or the percentage of motile or abnormal sperm. The mean body weight of the 3.5% dosed F0 females was significantly decreased relative to the control females. The magnitude of this decrease was approximately 7%. These animals also exhibited significantly decreased absolute liver and pituitary weights, but their organ-to body weight ratios were not different from controls. There were no significant treatment-related gross or histopathological lesions in the organs examined from the male and female F0 mice (Williams et al., 1990) [Kl score = 2].

I. Developmental Toxicity

Time-pregnant CD rats were dosed by oral gavage with 0, 1,118, 4,472 or 8,944 mg/kg on gestational days 6-15. In the high-dose females, there were reduced body weight gain, reduced food consumption, increased water consumption, increased liver and kidney weights and histopathological changes in the kidney. The mid-dose females exhibited only increased water consumption. There were no treatment-related effects on corpora lutea or implantations. Foetal body weights were reduced in the high-dose animals. Total or individual external or visceral variations were similar between treated and control groups; however, individual skeletal variations were significantly increased in the mid- and high- dose groups. The pattern of delayed ossification was considered consistent with reduced foetal body weight. Malformations were similar between treated and control groups. The maternal and developmental NOELs for this study were considered to be 1,118 mg/kg/day (Ballantyne and Snellings, 2005) [Kl score = 2].

Time-pregnant CD-1 mice were dosed by oral gavage with 0, 559, 2,795 or 11,180 mg/kg/day during gestational days 6-15. In the high-dose females, there was mortality, clinical signs, and increased water consumption; only increased water consumption was observed in the mid-dose females. Foetal body weights were significantly reduced in the high-dose animals. There were no increases in variations or malformations between treated and control animals. The maternal and developmental NOELs were 559 and 2,795 mg/kg/day, respectively (Ballantyne and Snellings, 2005) [Kl score = 2].

Groups of 15 pregnant Himalayan rabbits were administered oral (gavage) doses of 0, 100, 400 or 1,000 mg/kg DEG on gestational days 7-19. No maternal toxicity was observed at any of the DEG doses administered. The foetal and litter incidence of skeletal, soft tissue and external anomalies or variations were comparable to those of the control and/or historical control groups. The authors set the maternal and developmental toxicity NOEL at greater than 1,000 mg/kg (Hellwig et al., 1995) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The lowest NOAEL reported in the repeat dose toxicity study is 105 mg/kg/day based on the 225-day rat dietary study. Although, there was a 13.2% increase in oxalate excretion at this dose level, this was considered a biomarker and not an indicator of toxicity. At 0.4% (the LOAEL), there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The NOAEL of 105 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x U_{FD})

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 105/(10 x 10 x 1 x 1 x 1) = 105/100 = 1.0 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (1.05 x 70 x 0.1)/2 = 3.7 mg/L

B. Cancer

A two-year study of in rats showed no carcinogenic effects when diethylene glycol was administered in drinking water (Hiasa et al., 1990). In older studies, bladder tumours were observed in rats given diethylene glycol in feed; the tumours are considered to be the result of physical irritation from the bladder stones that also were noted in the same animals (Fitzhugh and Nelson, 1946; Weil et al., 1965). It cannot be ruled out that these older studies, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on diethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Diethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	75,200	2	ECHA
Oncorhynchus mykiss	96-hour LC_{5}	66,000	2	ECHA
Daphnia magna	24-hour EC_{50}	>10,000	2	ECHA
Daphnia magna	48-hour EC_{50}	65,980	2	ECHA
Daphnia magna	48-hour EC_{50}	62,630	2	ECHA

Chronic Studies

In ECHA, the aquatic toxicity of the 'ethylene glycol and higher glycols' (mono-, di-, tri-, tetra- and pentaethylene glycol) is evaluated in a read-across approach. Data on all three trophic levels (fish, *daphnia*, algae) are available to describe the aquatic toxicity of the glycol read-across members. Due to the fact, that not for each single substance data for all required endpoints are available, a weight of evidence approach is used, which includes additional information based on QSAR calculation with the EpiWin-Program ECOSAR v1.11. Measured data, as well as estimated data, demonstrate that all glycols within the read-across are not harmful to aquatic organisms. No adverse effects on aquatic organisms occurred up to concentrations above 100 mg/L (ECHA).

No data for fish was available for diethylene glycol. However, chronic studies for fish are available for ethylene glycol (CAS No.: 107-21-1). The 7-day NOEC for the fathead minnow (*Pimephales promelas*) was determined to be 15,380 mg/L based on the weight of the test organisms (ECHA) [Kl Score = 2].

No data for invertebrates was available for diethylene glycol. However, three studies were conducted with Dapnids (*Ceriodaphnia dubia* or *Daphnia magna*) for ethylene glycol (CAS-No.: 107-21-1) or triethylene glycol (CAS No.: 112-27-6). The study with ethylene glycol was conducted according to USEPA guideline 600/4-89/001 with *Ceriodaphnia dubia* as test species. The 7-day NOEC for reproduction was determined to be 8,590 mg/L ethylene glycol (nominal). Two studies

measured the effect of triethylene glycol on the reproduction of *Daphnia magna*. One study was conducted according to the national standard ASTM (E 47.01, Draft No. 1, "Draft proposed standard practice for conducting renewal life cycle toxicity tests with Daphnia magna"). In this test the Daphnids were exposed to triethylene glycol for 21 days. Based on reproduction the reported NOEC is > 15,000 mg/L triethylene glycol (nominal) (ECHA) [KI Score = 2].

Data for algae was available for diethylene glycol. The 8-day TGK to algae *Scenedesmus quadricauda* was determined to be 2,700 mg/L for diethylene glycol (ECHA) [KI score = 2].

From the QSAR calculations it can be expected for diethylene glycol that algae are slightly more sensitive (ChV = 1,200 mg/L) than invertebrates (ChV = 1,891 mg/L) or fishes (ChV = 7,694 mg/L) (ECHA) [KI Score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for diethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C50 values are available for fish (66,000 mg/L), and Daphnia (> 10,000 mg/L). Results from a chronic algae study is available on diethylene glycol (2,700 mg/L). On the basis that the data consists of short-term results from two trophic levels and a long-term result from one trophic level, an assessment factor of 100 has been applied to the lowest reported value, which is the chronic value for algae. The $PNEC_{water}$ is 27 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 17.3 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.89/1280) \times 1000 \times 27$
$= 17.3$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.89\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.36 mg/kg soil dry weight.

The calculations are as follows:

$PNECsoil = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 27

= 0.36 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diethylene glycol has been shown to be readily biodegradable; thus, it does not meet the screening criteria for persistence.

The calculated log K_{ow} is -1.98, and the experimental BCF is 100. Thus, diethylene glycol does not meet the screening criteria for bioaccumulation.

The lowest chronic toxicity value for diethylene glycol is > 0.1 mg/L. Thus, diethylene glycol does not meet the criteria for toxicity.

Therefore, diethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELING (ABSTRACTED FROM PUBCHEM)

A. Classification

Irritant

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS) (ABSTRACTED FROM PUBCHEM)

A. First Aid

Eye Contact

First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.\

Skin Contact

IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Inhalation

IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

Ingestion

DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious,

do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport the victim to a hospital.

Notes to Physician (abstracted from PubChem)

The patient should be resuscitated with isotonic crystalloidal fluids, and acidosis should be corrected. Early treatment with a competitive ADH inhibitor (e.g., 4-methylpyrazole or ethanol), hemodialysis and supportive care offer the best hope for patient recovery.

Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand-valve resuscitator, bag-valve-mask device or pocket mask, as trained. Perform CPR as necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature.

Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary oedema and treat if necessary. Monitor for shock and treat if necessary. Anticipate seizures and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex and does not drool. Administer activated charcoal.

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary oedema or is in severe respiratory distress. Positive-pressure ventilation techniques with a bag-valve-mask device may be beneficial. Consider drug therapy for pulmonary oedema. Monitor cardiac rhythm and treat arrhythmias if necessary. Start IV administration of D5W /SRP: "To keep open", minimal flow rate. Use 0.9% saline (NS) lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload. Treat seizures with diazepam or lorazepam. Use proparacaine hydrochloride to assist eye irrigation.

Medical Conditions Aggravated by Exposure

Respiratory conditions (asthma, etc.)

Emergency Personnel Protection

Wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Use water spray to keep fire-exposed containers cool.

B. Fire Fighting Information (abstracted from Comet Chemical SDS 2013)

Extinguishing Media

Use powder, alcohol-resistant foam, water spray, carbon dioxide.

Specific Exposure Hazards

Combustible when exposed to heat or flame; can react with oxidising materials.

Special Protective Equipment for Firefighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

C. Accidental Release Measures

Personal Precautions

Restrict access to area until completion of clean-up. Ensure clean-up is conducted by trained personnel only. All persons dealing with clean-up should wear the appropriate protective equipment including self-contained breathing apparatus.

Environmental Precautions

Ventilate the area. Stop spill or leak at source if safely possible. Dike for water control. Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g., sand), then place absorbent material into a container for later disposal.

Steps to be Taken if Material is Released or Spilled

Absorb spill with inert material (e.g., vermiculite, sand or earth), then place in suitable container. Clean up spills immediately, observing precautions in the Protective Equipment section. Provide ventilation.

D. Storage and Handling

General Handling

Wear protective gloves/clothing and eye/face protection. Use with adequate ventilation. Do not ingest. Do not breathe mist or vapour. Avoid contact with eyes, skin and clothing. Wash with soap and water after handling. Keep away from extreme heat and flame. Keep away from acids and other incompatibles. Keep containers tightly closed when not in use.

Other Handling Precautions

Wash thoroughly after handling. Use with adequate ventilation. Avoid breathing vapours from heated material. Avoid contact with eyes, skin and clothing. Keep container tightly closed. Wash clothing before reuse. Avoid breathing spray or mist.

Storage

Store in a cool, dry, well-ventilated area. Store away from areas of excessive heat, open flames, sparks and other possible sources of ignition. Keep away from incompatibles. Storage area should be

clearly identified, clear of obstruction and accessible only to trained and authorised personnel. Inspect periodically for damage or leaks.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for diethylene glycol.

Engineering Controls

Good general ventilation should be used. Localised ventilation should be used where vapours, mist or aerosols may be generated.

Personal Protection Equipment

Respiratory Protection: Wear an approved respirator with dust/mist pre-filters if any exposure to dust or mist is possible.

Hand Protection: Wear appropriate chemical-resistant gloves.

Skin Protection: Wear protective clothing to minimise skin contact.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Ballantyne, B., and Snellings, W.M. (2005). Developmental toxicity study with diethylene glycol by gavage to CD rats and CD-1 mice. Food Chem. Toxicol. 43: 1637-1646.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fitzhugh, O.G., and Nelson, A. (1946). Comparison of the chronic toxicity of triethylene glycol with that of diethylene glycol. J. Ind. Hyg. Tox. 25: 40-43.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. An experimental method for the assessment of the behavior of organic chemicals in the ecosphere by means of simple laboratory tests with 14C labeled chemicals. Chemosphere 14: 1589-1616.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Sci. 4: 67-80.

Hellwig, J., Klimisch, H.J., and Jäckh, R. (1995). Investigation of the prenatal toxicity of orally administered diethylene glycol in rabbits. Fundam. Appl. Toxicol. 28: 27-33. (1995).

Hiasa, Y., Kitahori, Y., Morimoto, J., Konishi, W., and Ohshima, M. (1990). Absence of carcinogenic or promoting effects of diethylene glycol on renal tumourigenesis in rats. J. Toxicol. Pathol. 3: 97-104.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Laug, E., Calvery, H.O., Morris, H.J., and Woodward, G. (1939). The toxicology of some glycols and derivatives. J. Ind. Hyg. Toxicol. 21: 173-201.

Lenk, W., Löhr, D., and Sonnenbichler, J. (1989). Pharmacokinetics and biotransformation of diethylene glycol and ethylene glycol in the rat. Xenobiotica 19: 961-979.

OECD. (2007). SIDS Dossier on the HPV Chemical Diethylene Glycol (CAS No. 111-46-6).

Pubchem. https://pubchem.ncbi.nlm.nih.gov/compound/DI_Hydroxyethyl_ether#section=InChI Accessed January 2022.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Verschueren, K. (1983). Handbook of Environmental Data on Organic Chemicals, 2nd Edition, Van Nostrand, New York: 1,310

Wegener, H. (1953). The reproductive capacity of rats after the action of diethylene glycol. Arch. Exper. Path. u. Pharmakol. 220: 414-417.

Weil, C.S., Carpenter, C. and Smyth, H.F. (1965). Urinary bladder response to diethylene glycol. Arch. Environ. Health 77: 569-581.

Williams, J., Reel, J., George, J., and Lamb, IV, J. (1990). Reproductive effects of diethylene glycol and diethylene glycol monoethyl ether in Swiss CD-1 mice assessed by a continuous breeding protocol. Fundam. App. Toxicol. 74: 622-635.

POTASSIUM CHLORIDE

This dossier on potassium chloride presents the most critical studies pertinent to the risk assessment of potassium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on potassium chloride (OECD, 2001a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Potassium chloride

CAS RN: 7747-40-7

Molecular formula: KCl

Molecular weight: 74.55 g/mol

Synonyms: Potassium chloride

SMILES: [Cl-] [K+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Potassium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid; white crystals	2	ECHA
Melting Point	770°C @ 101.3 kPa	1	ECHA
Boiling Point	1,407°C (pressure not provided)	2	OECD, 2001a,b
Density	1984 kg/m^3	2	ECHA
Vapour Pressure	5.73 hPa @ 906°C	2	OECD, 2001a,b
Partition Coefficient (log Kow)	-	-	-
Water Solubility	255 g/L @ 25°C	2	Lide, 2009; ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Potassium chloride (KCl) dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of potassium (K^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH and organic matter. Potassium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (OECD, 2001b).

Potassium (K^+) and chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001b; Ganong, 1995). Neither potassium chloride nor its dissociated ions are expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Potassium chloride has low acute toxicity by the oral route. It is not a skin or eye irritant. Long-term studies in rats fed potassium chloride showed no systemic toxicity or carcinogenic effects. Potassium chloride has shown some genotoxic effects in *in vitro* assays; these occurred at high concentrations of potassium chloride and is thought to be due to a disruption of the osmotic balance of the cells. No *in vivo* genotoxicity studies have been conducted on potassium chloride. There were no developmental effects in pregnant female rats and mice given potassium chloride in their diet.

B. Toxicokinetics and Metabolism

Potassium chloride dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium is an essential nutrient: it has a number of critical roles, one of which is that it is the principal cation involved in maintaining the osmotic balance of bodily fluids (Ganong, 1995). Both potassium and chloride ions are involved in regulating the acid-base balance of the body (Ganong, 1995).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 3,020 mg/kg (Boyd and Shanas, 1961) [Kl score = 2].

No acute toxicity studies by the dermal or inhalation route were identified.

D. Irritation

Potassium chloride did not produce an irritant response in an *in vitro* skin irritation (OECD TG 439) test (ECHA) [Kl score = 1].

Potassium chloride did not produce an irritant response in an *in vitro* eye irritation test (ECHA) [Kl score = 2].

E. Sensitisation

No studies were identified.

F. Repeated Dose Toxicity

<u>Oral</u>

Male F344/Slc rats were given 0, 0.25, 1, 5 or 5% potassium chloride in their feed for two years. The mean daily intake was calculated to be 0, 110, 450 or 1,820 mg/kg/day, respectively. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the respective dose groups. Nephritis was predominant in all groups, including the controls. The only treatment-related effect was gastritis (inflammation of the stomach lining). The incidence of gastritis and ulcers were 6%, 18%, 18% and 30% in the 0, 110, 450 and 1,820 mg/kg/day groups, respectively. The gastritis was thought to be indicative of a localised effect due to the irritating nature of the test material. The NOAEL for

systemic effects is 1,820 mg/kg/day, the highest dose tested (Imai et al., 1968; OECD 2001a,b) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. Due to the reduction of feed intake, the mean test substance intake and mean body weight decreased in time. The mean daily intake of potassium chloride was not calculated. There was hypertrophy of the zona glomerulosa in the adrenals (24/50 treated rats versus 4/50 in controls); and cystitis in the urinary bladder (males: 3/59; females 3/50) and single epithelial hyperplasia of the bladder (males 3/50; females 2/50) (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

G. Genotoxicity

In Vitro Studies

Potassium chloride was not mutagenic to *Salmonella typhimurium* strains TA100, TA 1535, TA 1537 and TA 98 strains in an *in vitro* bacterial mutation assay in the absence or presence of metabolic activation (Mortelmans et al., 1986).

Potassium chloride was weakly mutagenic in two separate L5178Y mouse lymphoma assays (Myhr and Caspary,1988; Mitchell et al., 1988). It was mutagenic at 4,000 and 5,000 μg/mL in the presence of metabolic activation in one study, and mutagenic at 7,000 μg/mL in the absence of metabolic activation. The authors stated that these responses are due to high salt concentrations which affect the ionic balance and osmotic pressure of the medium, inducing mutations in cells surviving the treatment.

Potassium chloride induced a significant increase in chromosomal aberrations in Chinese Hamster lung fibroblasts (V79) cells only at the highest test dose (12,000 μg/mL) in the absence of a metabolic activation system. Measurements of the osmotic pressure of the medium showed a two-fold increase at this test compound concentration when compared to the normal medium (530 mOsmol/kg versus 253 mOsmol/kg) (OECD, 2001b).

There are two other reports on the effect of potassium chloride on the formation of chromosome aberrations in Chinese hamster ovary cells (CHO). In these studies potassium chloride concentrations of 75 and 80 mM (approximately 5,500 and 6,000 μg/mL) resulted in 19% and 28% aberrant cells, respectively. An increased number of chromosome aberrations was observed with potassium chloride concentrations that reduced cell survival of 40% or more. The increases in mutagenicity and chromosome aberrations observed in these studies have been considered to be related to cytotoxicity resulting from the high potassium chloride concentrations used (Brusick, 1988).

The reported mutagenic effect of potassium chloride most probably results from a disruption of the osmotic balance of cells with a subsequent interference with chromosomal stability. This may result in the clastogenic effects (DNA breakage and chromosome structural instability) due to K^+ effects on sequestering of Mg^{++} ions required for normal maintenance of chromatin integrity (OECD, 2001b).

In Vivo Studies

No studies have been identified.

H. Carcinogenicity

Oral

F344/Slc male rats were given 0, 110, 450 or 1,820 mg/kg/day potassium chloride in feed for two years. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the 0, 110, 45 and 1,820 mg/kg/day groups. There was no increased incidence of tumours that were considered to be treatment-related (Imai et al., 1968) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. There were no treatment-related differences in tumour response among the groups (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

I. Reproductive Toxicity

No studies were identified.

J. Developmental Toxicity

Pregnant Wistar rats were given doses of 3.1 to 310 mg/kg potassium chloride by oral gavage during gestation days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 310 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

Pregnant CD-1 mice were given doses of 2.35 to 235 mg/kg potassium chloride by oral gavage during gestation Days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 235 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for potassium chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Two chronic rat feeding studies have been conducted on potassium chloride: only the study by Imai et al. (19686 was conducted with multiple doses and provided mean daily intake values. In this study, the only treatment-related effects were associated with chronic irritation in the gastrointestinal tract (gastritis and ulcers), a localised effect due to the irritating properties of the test material. No systemic toxicity was observed at any of the doses tested. The NOAEL for systemic toxicity in this study is 1,820 mg/kg/day, the highest dose tested. The NOAEL of 1,820 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subacute to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4(10 x 10 x 1 x 1 x 1) = 1,820/100 = 18 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD:

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (18 x 70 x 0.1)/2 = 63 mg/L

Australian Drinking Water Guidelines

The Australian drinking water guideline value for chloride is 250 mg/L based on aesthetics (ADWG, 2011).

B. Cancer

Potassium chloride was not carcinogenic to rats in two chronic feeding studies. Therefore, no cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Potassium chloride does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Potassium chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

The results of the acute toxicity studies conducted on potassium chloride are presented in Table 2.

Table 2: Acute Aquatic Toxicity Studies on Potassium Chloride

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	880	2	Mount et al., 1997; ECHA
Daphnia magna	48-hour EC_{50}	660	2	Mount et al., 1997; ECHA
Ceriodaphnia dubia	48-hour EC_{50}	630	2	Mount et al., 1997; ECHA
Scenedesmus subspicatus	72-hour EC_{50}	> 100* (growth rate)	1	ECHA

*NOEC = > 100 mg/L

Chronic Studies

In a fish early-life-stage test with the fathead minnow (*Pimephales promelas*), the 7-day NOEC was 500 mg/L (ECHA).

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (820 mg/L), *Daphnia* (660 mg/L) and algae (> 100 mg/L). Although a chronic study was conducted on fish that fulfils the requirements in the OECD TG 210, it is not considered adequate for deriving a PNEC because of the short duration of the test. On the basis of the short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported effect concentration of 100 mg/L for algae. The $PNEC_{water}$ is 1.0 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Potassium chloride dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of potassium chloride to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of potassium chloride is dominated by its water solubility. Sorption of potassium chloride should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, potassium chloride is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Potassium chloride is an inorganic salt that dissociates completely to potassium and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both potassium and chloride ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Potassium and chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Therefore, potassium chloride is not expected to bioaccumulate.

There are no adequate chronic aquatic toxicity studies available on potassium chloride. The acute $E(L)C_{50}$ values for potassium chloride are > 1 mg/L in fish, invertebrates and algae. Therefore, potassium chloride does not meet the screening criteria for toxicity.

The overall conclusion is that potassium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact

Wash with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Do not induce vomiting. Rinse mouth with water and then drink a small amount of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Firefighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: potassium oxides, hydrogen chloride, chlorine gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for potassium chloride.

Engineering Controls

Use in a well-ventilated area.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Potassium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Boyd, E.M., and Shanas, M.N. (1961). The acute oral toxicity of potassium chloride. Arch. Int. Pharmacodyn. Ther. 133: 275-283.

Brusick, D. (1988). Genotoxic effects in cultured mammalian cells produced by low pH treatment conditions and increased ion concentrations. Environ. Mutag. 8: 879-886.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

FDRL. (1975). Teratological evaluation of FDA 73-78 (KCl) in mice and rats. Final report prepared under DHEW. Contract No. FDA 223-74-2176 by Food and Drug Research Laboratories Inc. Waverly, New York.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Imai, S., Morimoto, J., Sekiya, N., Shima, M., Kiyozuka, Y., Nakamori, K., Tsubura, Y. (1986). Chronic toxicity test of KCl and NaCl in F344/Scl rats. J. Nara Med. Ass. 37:115-127 [in Japanese]; cited in OECD 2001a,b.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

Lina, B.A.R., and Kuijpers, M.H.M. (2004). Toxicity and carcinogenicity of acidogenic or alkalogenic diets in rats; effects of feeding NH_4Cl, $KHCO_3$ or KCl. Food Chem. Toxicol. 42: 135-153.

Mitchell, A.D., Rudd, C.J., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at SRI international. Env. Molecular Mutagenesis 12(13):37-101.

Mortelmans, K., Haworth, S., Lawlor, T., Speck, W., Tainer, B., Zeiger, E. (1986). Salmonella mutagenicity tests: II. Results from the testing of 270 chemicals. Env. Mutagenesis 8(7):1-119.

Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., and Evans, J.M. (1997). Statistical models to predict the toxicity of major ions to *Ceriodaphnia dubia, Daphnia magna* and *Pimephales promelas* (fathead minnows). Environ. Toxicol. Chem. 16: 2009-2019.

Myhr, B.C., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at Litton Bionetics, Inc. Env. Molecular Mutagenesis. 12(13):103-194.

OECD. (2001a). IUCLID Data Set for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

OECD. (2001b). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

Appendix C.3 January 2022 Risk Dossiers

2-PROPENAMID (IMPURITY)

This dossier on 2-Propenamid (impurity) (2PA) (CAS RN 79-06-1) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): prop-2-enamide

CAS RN**:** 79-06-1

Molecular formula: C_3H_5NO

Molecular weight: 71.08 g/mol

Synonyms: 2-Propenamide; Acrylamide; Acrylamide solution 50%; EUROAMD

SMILES: C=CC(=O)N

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of 2PA

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Crystalline White solid	1	ECHA
Melting Point	84.5°C at 101.3 kPa	1	ECHA
Boiling Point	Not applicable as substance is solid	1	ECHA
Density	1130 kg/m^3 at 30°C	2	ECHA
Vapour Pressure	Not applicable as substance is solid	1	ECHA
Partition Coefficient (log K_{ow})	-0.9 at 20°C	1	ECHA
Water Solubility	2,155 g/L at 30°C	1	ECHA
Flash Point	Not applicable as substance is solid	1	ECHA
Auto flammability	Not applicable as substance is solid	1	ECHA
Viscosity	Not applicable as substance is solid	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

2-Propenamid is expected to biodegrade and is not expected to sorb substantially to soils or sediments based on the low log K_{ow} and K_{oc} values. In addition, 2-propenamid is not expected to bioaccumulate.

B. Biodegradation

2PA was found to degrade approximately 100% in 28 days in the OECD Closed Bottle Test (301D) (ECHA) [KI Score = 1].

C. Environmental Distribution

No data available (ECHA). However, K_{oc} values of 3.554 L/kg (K_{ow} method) and 5.694 L/kg (MCI method) were estimated using USEPA EPI Suite™ KOCWIN v2.00 module. The estimated log K_{oc} values equal 0.551 and 0.755 for the K_{ow} and MCI methods, respectively [KI Score = 2]. Based on these estimated values, the substance is not expected to sorb substantially to soils or sediments.

D. Bioaccumulation

No experimental data were available for bioaccumulation or bioconcentration of 2PA. However, the log bioaccumulation factor (BAF) determined from regression-based calculations were performed using EPI Suite BCFBAF v3.01. Based on a log K_{ow} of -0.67, the log BAF according to the Arnot-Gobas method for assessing bioaccumulation at the upper trophic level was determined to be -0.047 [KI Score = 2]. The relatively low log BAF suggests 2PA will not bioaccumulate to any substantial degree.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of 2PA is low by the oral, inhalation and dermal routes. It is not irritating to the eyes or skin and is not a skin sensitiser. Repeated exposures of 2PA to rats in a chronic drinking water study exhibited neurotoxicity and carcinogenicity. *In vitro* and *in vivo* studies provide strong evidence that 2PA does not react directly with DNA. It has no reported reproductive or developmental effects.

B. Acute Toxicity

<u>Oral</u>

An EU Method B.1 (Acute Toxicity Oral) study was performed on Sprague-Dawley rats exposed to 2PA. Under the experimental conditions, the oral LD_{50} in rats of acrylamide in aqueous solution at 50% was 354 mg/kg in female rats with 95% confidence interval limits of 305-458 mg/kg. Toxicity was comparable in males. In accordance with the ethic and scientific recommendations concerning the LD_{50} a more precise determination was not conducted. Based on the results of this study, it can be concluded that the acute oral LD_{50} of acrylamide in rats is 177 mg/kg (ECHA) [KI score =1].

Inhalation

An OECD Guideline 433 draft (Acute Inhalation Toxicity: Fixed Concentration Procedure) was employed to estimate the acute inhalation toxicity of 2PA to an unspecified strain of male rat. The results of this test indicate that the 50.7% solution of acrylamide is practically non-toxic by the inhalation route with a LC_0 (60 mins) of 12 mg/L (ECHA) [KI score =2].

Dermal

An OECD Guideline 402 – Acute Dermal Toxicity was employed to estimate the acute dermal toxicity of 2PA to a non-specified strain of rabbit. Rabbits were occlusively dosed at 200, 795, 1,580 and 3,160 mg/kg of 50.7% aqueous acrylamide solution. Solution was applied to unabraided skin. The acute dermal LD_{50} for acrylamide was determined to be 1,141 mg acrylamide/kg bw (ECHA) [KI Score=1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of 2PA using New Zealand White rabbits. Shaved areas of three male animals were treated with 0.5 g per animal of the test article prepared as a paste with 0.086 g of water. A semi-occlusive patch was overwrapped with a gauze binder and secured with tape for an exposure period of 4 hours. Post dosing, excess test article which had not penetrated was wiped away with a gauze pad moistened with water. Animals were observed for 1, 24, 48 and 72 hours after the removal of the bandage. Scoring was conducted according to the scale published in the OECD Guideline (No. 404 – 1992).

Neither erythema nor oedema was observed at any time. It can be concluded from the results obtained under the experimental conditions employed that acrylamide is not irritating to skin (ECHA) [KI score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using 2PA. Three male New Zealand White rabbits received 0.1 mL of undiluted solution in one eye. The other eye remained untreated. The exposure period was 24 hours. Reactions were scored at 1, 24, 48 and 72 hours and at 7, 14 and 21 days post-application to evaluate reversibility of the lesions.

Maximum conjunctivae, chemosis, iris and corneal opacity scores were 2, 2, 1 and 2.3, respectively, which were found to be fully reversible up to 21 days post exposure.

There were no deaths or remarkable body weight changes during the study period. Under the study conditions, 2PA is considered to cause irritation to the eye (ECHA) [KI score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study (i.e., Buehler test) was performed on Pirbright-Hartley guinea pigs. Systemic toxic symptoms after application were not observed at any time during the study. Body weight development was positive and within normal ranges. No erythema nor oedema was observed at any point after the challenge application

in the control group. There were apparently no skin reactions in control animals but 85% of test animals gave a positive response. On the basis of these results, acrylamide should be considered a skin sensitiser in animals (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed using Fischer 344 rats. 2PA was administered orally in drinking water for a period of two years. Dosing levels were given at 0.0, 0.01, 0.1, 0.5 and 2.0 mg/kg/day.

The rats were generally observed twice daily during the work week for overt signs of toxicity or changes in demeanour. These observations included the animals' movement within the cage, the availability of food and water, wastage of feed and the response to the opening and closing of the cage. Routine monitoring on weekends and holidays was limited to the removal of dead animals and animal husbandry procedures required to ensure the availability of food and water.

Parameters monitored during the study included mortality, body weight, food consumption, water consumption, clinical observations, haematology, clinical chemistry, urinalysis, organ weights, gross and histopathology. All rats were examined approximately monthly after the first month for palpable masses. Individual body weights were recorded monthly from all rats.

Overall, ingestion of 2PA induced neurotoxicity in F344 rats at doses ranging from 0.01-2.0 mg/kg/day. Testicular atrophy was observed in rats at elevated doses. The No Observed Adverse Effect Level (NOAEL) was determined to be 0.5 mg/kg in both sexes of rats (ECHA) [KI Score = 1].

Inhalation

No data were available.

Dermal

No data were available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on 2PA based are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on 2PA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Bacterial Reverse Mutation Assay)	-	-	2	ECHA

*+, positive; -, negative.

In Vivo Studies

Acrylamide has been extensively tested in a wide variety of *in vitro* and *in vivo* assays for detection of genetic effects. There is no compelling evidence that acrylamide induces point mutations or interacts with DNA *in vivo* to form DNA adducts. In contrast to point mutation and DNA damage assays, acrylamide induces a variety of chromosomal effects in bone marrow, but studies in spermatogonia are conflicting. Dominant lethal assays have generally produced positive results with acrylamide, which could be explained by chromosomal effects such as deletions. These studies, taken together, provide very strong evidence that acrylamide does not react directly with DNA (ECHA) [Kl Score = 4].

G. Carcinogenicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed using Fischer 344 rats. 2PA was administered orally in drinking water for a period of two years. Dosing levels were given at 0.0, 0.01, 0.1, 0.5 and 2.0 mg/kg/day.

Overall, ingestion of 2PA induced benign thyroid, mammary gland and tunica vaginalis tumours. The NOAEL was determined to be 0.5 mg/kg in both sexes of rats (ECHA) [Kl Score = 1].

Despite National Toxicology Program conclusions that long-term dosing studies using 2PA provide clear evidence of carcinogenicity in rats, the cited study results provided in this dossier are equivocal relative to cancer responses. When evaluating a human relevance table, none of these tumors appear relevant to humans. Humans have substantially different mammary gland physiology from rodents and the tunica vaginalis tumors appear specific for the F344 rat. Only the thyroid may have significance (ECHA).

It should be noted that according to National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2002) acrylamide meets the National Occupational Health and Safety Commission (NOHSC) Approved Criteria (NOHSC, 1999) for classification as a Category 2 carcinogen (Risk Phrase R45 – May cause cancer).

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

Oral

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed on male and female Fischer 344 rats. 2PA was administered orally in drinking water at 0, 0.5, 2.0 or 5.0 mg/kg/day.

Long-term exposure to 2PA in the drinking water, over two generations in Fischer 344 rats, resulted in parental toxicity (reduced bodyweight, clinical signs of toxicity, histologic evidence of axonal swelling and/or degeneration in peripheral nerves) at 5.0 mg/kg/day, accompanied by prenatal lethality. Exposure to 2.0 mg/kg/day resulted in similar but lesser adult toxicity but no prenatal lethality. Exposure to 2.0 mg/kg/day resulted in no change to reproductive parameters in either generation except for reduced body weights and weight gain in F0 males in the pre-breed exposure period and reduced body weight and weight gain in F0 females late in the pre-breed exposure period. The only significant reproductive event induced by 2PA was decreased litter size as a result of dominant lethal mutations.

The NOAEL for all generations was determined to be 2 mg/kg/day (ECHA) [Kl Score = 1].

I. Developmental Toxicity

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed on Sprague-Dawley rats. Animals were dosed daily via oral gavage at 0, 2.5, 7.5 and 15 mg/kg.

Maternal Effects

There were no maternal mortalities and no clear clinical signs of toxicity. When corrected for gravid uterine weight, maternal body weight gain was decreased amongst animals receiving 7.5 and 15 mg/kg/day. The NOAEL for maternal toxicity was determined to be 2.5 mg/kg bw/day.

Developmental Effects

There were no apparent effects on embryo/foetal viability, growth or malformations. There was a slight, but not statistically significant, increase in the incidence of skeletal variations. The most frequently observed variation was the presence of a rudimentary extra lumbar rib. This finding is considered likely to be an indirect consequence of maternal toxicity or stress and is of limited toxicological importance. The NOAEL for developmental effects was determined to be 15 mg/kg bw/day (ECHA) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for 2PA follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Based on health considerations, the concentration of acrylamide in drinking water should not exceed 0.0002 mg/L according to Australian Drinking Water Guidelines Version 3.4. The guideline value for acrylamide of 0.0002 mg/L is based on a consideration of health effects in relation to the limit of determination for analysis using commonly available techniques.

Based on strict health related factors, a health-based derivation was determined as 0.0007 mg/L according to Australian Drinking Water Guidelines Version 3.4. A safety factor of 1,000 is used for the results of an animal study as a basis for human exposure (10 for interspecies variations, 10 for intraspecies variations and 10 for a less than lifetime study). An additional factor of 10 for carcinogenicity was not applied as tumours occur at doses above those that cause neurotoxic effects. The use of this safety factor was recommended by the NHMRC Standing Committee on Toxicity.

B. Cancer

An oral cancer slope factor for 2PA of 5×10^{-1} per mg/kg/day has been developed by USEPA and presented in the Integrated Risk Information System (IRIS) based on thyroid tumours and tunica vaginalis mesotheliomas (USEPA). Health based values will not be derived based on the noted slope factor since NICNAS has determined that the above noted drinking water guidance value is protective of both non-cancer and cancer effects.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2PA does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2PA has low acute and chronic aquatic toxicity.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on 2PA.

Table 3: Acute Aquatic Toxicity Studies on 2PA[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Onchorhyncus mykiss	96-hour LC_{50}	180	1	ECHA
Daphnia magna	48-hour EC_{50}	60	1	ECHA

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pseudokirchneriella subcapitata	72-hour EC_{50}	33 (growth inhibition) 50 (growth rate inhibition)	2	ECHA

Chronic Studies

Fish: A 28-day study was conducted to determine the toxicity of acrylamide monomer to carp (*Cyprinus carpio*). Fish were exposed to 2PA at concentrations of 0, 0.05, 0.5 and 5 mg/L. The NOEC was determined to be 5 mg/L (ECHA) [Kl Score = 2].

Invertebrates: No freshwater invertebrate chronic toxicity data were available (ECHA) [Kl Score = 1].

C. Terrestrial Toxicity

No data were available.

D. Calculation of PNEC

The PNEC calculations for 2PA follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (180mg/L), Daphnia (60 mg/L), and algae (33 mg/L). NOEC values from long-term studies are available for fish (5 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term studies from one trophic level, an assessment factor of 100 has been applied to the lowest reported NOEC value of 5 mg/L. Therefore, the $PNEC_{water}$ is 0.05 mg/L.

PNEC sediment

2PA is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and K_{oc} values, the substance is not expected to bind substantially to sediment. Therefore, a PNEC for sediment has not been calculated.

PNEC soil

2PA is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and K_{oc} values, the substance is not expected to bind substantially to soil. Therefore, a PNEC for soil has not been calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

2PA is an organic substance that has been determined to be readily biodegradable. Thus, it does not meet the screening criteria for persistence.

The relatively low log BAF (-0.047) suggests 2PA will not bioaccumulate to any substantial degree. Therefore, 2PA does not meet the screening criterion for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on 2-PA are > 0.1 mg/L. The acute $E(L)C_{50}$ values from the acute aquatic toxicity studies on 2-PA are > 1 mg/L. Thus, 2-PA does not meet the criteria for toxicity.

Based on PBT assessment guidance cited above, 2PA is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Oral – Acute Tox. 3: H301: Toxic if swallowed.

Dermal – Acute Tox. 4: H312: Harmful in contact with skin.

Inhalation – Acute Tox. 4: H332: Harmful if inhaled.

Skin corrosion / irritation – Skin Irrit. 2: H315: Causes skin irritation.

Serious eye damage / eye irritation – Eye Irrit. 2: H319: Causes serious eye irritation.

Skin sensitisation – Skin Sens. 1: H317: May cause an allergic skin reaction.

Reproductive toxicity: H361: Suspected of damaging fertility or the unborn child.

Germ cell mutagenicity: H340: May cause genetic defects.

Carcinogenicity: H350: May cause cancer.

Specific target organ toxicity: STOT Rep. Exp. 1: H372: Causes damage to organs.

B. Signal word

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if

ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standards for 2-PA in Australia is 0.03 mg/m^3 as am 8-hour time weighted average (TWA). There is also a skin notation indicating that absorption through the skin may be significant source of exposure.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: 2074 (Solid)

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). European Centre for Ecotoxicology and Toxicology of Chemicals The Role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and the Related Food Web. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Technical Report No. 68, Brussels.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS. (2002). Acrylamide Priority existing Chemical Assessment Report No. 23.

NOHSC (National Occupational Health and Safety Commission). (1999). List of Designated Hazardous Substances [NOHSC:10005(1999)]. Sydney, NOHSC.

USEPA. The Integrated Risk Information System (IRIS). www.epa.gov/iris.

2-PROPENOIC ACID, POLYMER WITH SODIUM PHOSPHINATE (1:1), SODIUM SALT

This dossier on 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt in coal seam gas extraction activities. The majority of information presented in this dossier is based on a surrogate 2-propenoic acid, polymer with sodium phosphinate (CAS No. 71050-62-9). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Propenoic acid, polymer with sodium phosphinate (1:1), sodium salt

CAS RN: 129898-01-7

Molecular formula: $(C_3H_4O_2.H_3O_2\text{-}P.Na)_x$- x-Na

Molecular weight: Variable

Synonyms: 2-propenoic acid, polymer with sodium phosphinate, sodium salt; 2-propenoic acid polymer with sodium hypophosphite, sodium salt; 2-Propenoic acid, polymer with sodium hypophosphite, sodium salt

SMILES: Not applicable

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of 2-Propenoic acid, Polymer with Sodium Phosphinate (CAS No. 71050-62-9)

Property	Value	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	BWA, 2006
Melting Point	-1 to -3°C	BWA, 2006
Boiling Point	101 to 103°C	BWA, 2006
Specific Gravity	1.20 to 1.24	BWA, 2006
pH	3.5 to 4.5	BWA, 2006
Viscosity	75-200 mm^2/s @ 25°C	BWA, 2006
Water Solubility	Miscible	BWA, 2006

III. ENVIRONMENTAL FATE PROPERTIES

In an OECD 301E test, 2-propenoic acid, polymer with sodium phosphinate degraded 20% in 28 days, indicating that it is not readily biodegradable (BWA, 1999).

As a polymer, 2-propenoic acid, polymer with sodium phosphinate is not expected to bioaccumulate, because its molecular weight will limit its bioavailability.

IV. HUMAN HEALTH HAZARD ASSESSMENT

There is very limited information on 2-propenoic acid, polymer with sodium phosphinate.

A technical data sheet on Belsperse® 164 Dispersant (active ingredient: CAS No. 71050-62-9) lists this product as having an acute oral LD_{50} value of > 5,000 mg/kg in rats. The product is non-irritating to the skin and eyes (BWA, 2006).

In a letter to the U.S. EPA, male and female rats dosed by oral gavage with a 40% solution of this polymer showed treatment-related signs of osteomalacia associated with hyperphosphaturia and calciuria by week 8 of a 90-day study (U.S. EPA, 2016a).

The U.S. EPA TSCATS database also has a brief summary of a 4-week rat oral gavage conducted on the product BELSPERSE 164 (CAS No. 71050-62-9). At 5,000 mg/kg/day, there were adverse clinical signs, gross organ pathology and changes in blood biochemical parameters. The NOAEL was 2,000 mg/kg/day (U.S. EPA, 2016b).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on 2-propenoic acid, polymer with sodium phosphinate is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this polymer.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

2-Propenoic acid, polymer with sodium phosphinate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

2-Propenoic acid, polymer with sodium phosphinate exhibits low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on 2-propenoic acid, polymer with sodium phosphinate.

Table 2: Acute Aquatic Toxicity Studies on 2-Propenoic Acid, Polymer with Sodium Phosphinate (CAS No. 71050-62-9)

Test Species	Endpoint	Results (mg/L)	Reference
Rainbow trout	96-hour LC_{50}	> 1,000	BWA, 2006
Zebra fish	96-hour LC_{50}	> 1,000	BWA, 2006
Daphnia	24-hour EC_{50}	320	BWA, 2006
Algae	72-hour EC_{50}	130	BWA, 2006

Chronic Studies

No studies were located.

C. Terrestrial Toxicity

No studies were located.

D. Calculation of PNEC

The PNEC calculations for 2-propenoic acid, polymer with sodium phosphinate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (> 1,000 mg/L), *Daphnia* (> 320 mg/L) and algae (> 130 mg/L). No long-term studies on 2-propenoic acid, polymer with sodium phosphinate are available. On the basis of the short-term results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 130 mg/L for algae. The $PNEC_{water}$ is 0.13 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot estimate using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$.

PNEC soil

There are no toxicity data for soil-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for 2-propenoic acid, polymer with sodium phosphinate; these values cannot be estimated using QSAR models because of the high molecular weight of 2-propenoic acid, polymer with sodium phosphinate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Based on the information for read-across substance 2-Propenoic acid, polymer with sodium phosphinate, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not readily biodegradable. Thus, it meets the screening criteria for persistence.

Read-across substance 2-Propenoic acid, polymer with sodium phosphinate is a high molecular weight polymer that is not expected to be bioavailable to aquatic or terrestrial organisms. Thus, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt it is not expected to bioaccumulate.

No chronic aquatic toxicity studies have been conducted on read-across substance 2-propenoic acid, polymer with sodium phosphinate. The acute E(L)C_{50} values are > 1 mg/L. Thus, 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt does not meet the screening criteria for toxicity.

The overall conclusion is that 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictogram

None.

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, phosphorus oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing closed work clothing is recommended.

F. Transport Information

2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

BWA. (1999). BWA Water Additives. Belsperse® 164 Dispersant. General Product Information,

BWA. (2006). BWA Water Additives. Product Information for Belsperse 164 – High Performance Dispersant for Industrial Water Systems. 2006 BWA, V1010

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

U.S. EPA [EPA]. (2016a). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88900000038; accessed October 2016.

U.S. EPA [EPA]. (2016b). U.S. Environmental Protection Agency (EPA) Toxic Substance Control Act Test Submissions (TSCATS) database. DCN 88920001980; accessed October 2016.

ACRYLAMIDE, 2-ACRYLAMIDO-2-METHYLPROPANESULFONIC ACID, SODIUM SALT POLYMER (CAS RN 38193-60-1)
POLYMER OF 2-ACRYLAMIDO-2-METHYLPROPANESULFONIC ACID SODIUM SALT AND METHYL ACRYLATE (CAS RN 136793-29-8)

This group contains an acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer (CAS RN 38193-60-1) and polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate (CAS RN 136793-29-8). They are expected to have similar environmental concerns and have consequently been assessed as a group. Information provided in this dossier is based on data for the monomer sodium acryloyldimethyltaurate (CAS RN 5165-97-9).

This dossier presents the most critical studies pertinent to the risk assessment of these substances in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer

CAS RN: 38193-60-1

Molecular formula: (C7-H13-N-O4-S.C3-H5-N-O.Na)x-

Molecular weight: 302.32 g/mol (monomer); Based on the type and intended use, the molecular weight of the polymer would likely range from 1,000 to > 1,000,000 g/mol (CIR, 2017).

Synonyms: 1-Propanesulfonic acid, 2-methyl-2-((1-oxo-2-propen-1-yl)amino)-, sodium salt (1:1), polymer with 2-propenamide

SMILES: Not applicable

Chemical Name (IUPAC): Polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate

CAS RN: 136793-29-8

Molecular formula: (C7-H13-N-O4-S.C4-H6-O2.Na)x-

Molecular weight: 315.3202 g/mol (monomer); Based on the type and intended use, the molecular weight of the polymer would likely range from 1,000 to > 1,000,000 g/mol (CIR, 2017).

Synonyms: 2-Propenoic acid, 2-methyl-, polymer with 2-methyl-2-((1-oxo-2-propenyl)amino)-1-propanesulfonic acid monosodium salt

SMILES: Not applicable

Chemical Name (IUPAC): sodium;2-methyl-2-(prop-2-enoylamino)propane-1-sulfonate

CAS RN: 5165-97-9

Molecular formula: $C_7H_{12}NNaO_4S$

Molecular weight: 229.23 g/mol

Synonyms: 1-Propanesulfonic acid, 2-methyl-2-[(1-oxo-2-propenyl)amino]-, monosodium salt

SMILES: CC(C)(CS(=O)(=O)[O-])NC(=O)C=C.[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

NICNAS has assessed polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate in an IMAP Tier 1 assessment and considers it a polymer of low concern, and concluded that it poses no unreasonable risk to human health and the environment[1].

Physical and chemical properties were not available for either polymer: acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer (CAS RN 38193-60-1) or polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate (CAS RN 136793-29-8). Available information for the monomer is provided in Table 1.

Table 1: Overview of the Physico-chemical Properties of Sodium Acryloyldimethyltaurate (CAS RN 5165-97-9)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Light amber liquid @ 25°C with a faint organic odour	1	ECHA
Melting Point	-25°C @ 101.3 kPa	1	ECHA
Boiling Point	110°C @ 101.3 kPa	2	ECHA
Density	1200 - 1300 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	7.4 x 10^{-9} Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	-4.34 (temperature and pH not specified)	2	ECHA
Water Solubility	1000 g/L @ 25°C	2	ECHA
Flash Point	No data available	-	-
Auto flammability	No data available	-	-
Viscosity	0.6 mm^2/s @ 20°C	2	ECHA

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=38193-60-1

Property	Value	Klimisch score	Reference
Dissociation constant	No data available	-	-

III. ENVIRONMENTAL FATE PROPERTIES

No data is available for the polymers and limited studies are available for the monomer (sodium acryloyldimethyltaurate). The polymers are not expected to be readily biodegradable. The physico-chemical properties of the polymers would preclude it from undergoing significant biodegradation (Guiney et al., 1997). Biodegradation is limited due to the very high molecular weight and the low water solubility of the polymers. In addition, sodium acryloyldimethyltaurate was evaluated in a 44-day biodegradation in water study . This substance showed low biodegradation with a rate of less than 10% after 44 days (ECHA). [Kl. Score = 1]

Acryloyldimethyltaurate polymers are large (2000 µm; >1000 to >1,000,000 g/mol) molecules (CIR, 2017). Anionic polymers of this type will likely bind tightly to organic matter found within soils and sediments (Guiney et al., 1997). However, the polymers are not expected to bioaccumulate because of their poor water solubility and high molecular weight.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium acryloyldimethyltaurate has low acute toxicity by the oral and dermal routes. It is not a skin or eye irritant; and, it is not a skin sensitiser. No systemic toxic effects were observed in repeated dose subchronic oral toxicity studies. Sodium acryloyldimethyltaurate is not genotoxic and is not a developmental toxicant.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was performed. The study was conducted to determine the acute oral toxicity of sodium acryloyldimethyltaurate in Sprague-Dawley rats. Groups of 10 fasted animals (5 males and 5 females per dose except for 5 males only at the highest dose) were administered 0, 500, 1000, 2000, 4000, and 8000 mg/kg of the test substance via the oral route. The animals were observed for 14 days after dosing and then sacrificed and subjected to gross pathological examination. No unusual clinical or behavioural signs were observed in animals receiving dosages ranging from 1000-8000 mg/kg. Animals receiving 16000 mg/kg appeared ruffled and lethargic within 3-4 hours of test material administration. All animals appeared normal by day 5. No unscheduled deaths were recorded and gross examination revealed no pathological findings. There were no effects in the rat at the highest dose of 16,000 mg/kg. This is considered to be the No Observed Adverse Effect Level (NOAEL) (ECHA) [Kl. score =1].

The results from an OECD Guideline study (425) in rats showed that the LD_{50} > 5,000 mg/kg (> 1,200 mg/kg bw/day) for sodium acryloyldimethyltaurate (CIR, 2017).

Inhalation

No data was available.

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed using New Zealand White rabbits. Under the conditions of the test, The LD_{50} of the test substance (OS 114454) was found to be greater than 2000 mg/kg (based on active ingredient, 4000 mg/kg based on test substance) when administered once for 24 hours to the clipped, intact skin of male and female albino rabbits. In addition, 2000 mg/kg was found to be a No-Observable-Effect Level (NOEL) for systemic toxicity under the conditions of this study. (ECHA) [Kl Score=1].

The results from an OECD Guideline (402) study in rats showed that the dermal LD_{50} for sodium acryloyldimethyltaurate is > 5,000 mg/kg (1,200 mg/kg bw/day) (CIR, 2017).

C. Irritation

Skin

Sodium acryloyldimethyltaurate was determined to be a minimal dermal irritant to rabbits by the USEPA (OPPTS 870.2500, Acute Dermal Irritation) and a dermal non-irritant based on OECD Guideline 404 (ECHA). [KI Score = 1].

Eye

Sodium acryloyldimethyltaurate was determined to be slightly irritating to the eye based on an OECD 405 study (CIR, 2017). In a USEPA OPPTS 870.2400 (Acute Eye Irritation) test, sodium acryloyldimethyltaurate was determined to be not irritating to the eye (ECHA). [KI Score = 1].

D. Sensitisation

There was no evidence that sodium acryloyldimethyltaurate was sensitising to human (HRIPT test) or rats (OECD Guideline 406 study) (CIR, 2017).

An EU Method B.6 (Skin Sensitisation) study (i.e., guinea pig maximisation test) was performed on Dunkin-Hartley guinea pigs. Under the conditions of this study, the test substance (OS 114454) did not produce evidence of skin sensitisation (delayed contact hypersensitivity) in nine of the ten test animals. The remaining animal gave an inconclusive response. The test substance was considered to be non-sensitising (ECHA). [Kl. Score = 1].

E. Repeated Dose Toxicity

Oral

In an OECD Guideline (407) study, sodium acryloyldimethyltaurate was exposed to Sprague Dawley rats via oral gavage for 28 days at doses of 50, 150, 400 and 1000 mg/kg bw/day. No significant toxicity was observed at any dose level. The NOEL was determined to be 1,000 mg/kg bw/day (ECHA). [KI Score = 1].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on sodium acryloyldimethyltaurate are presented in Table 2. In general, the substance did not produce a significant increase in the number of revertants, with and without metabolic activation in any test strain (ECHA). [Kl. Score = 1]..

Table 2: *In Vitro* Genotoxicity Studies on sodium acryloyldimethyltaurate

Test System1	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Bacterial Reverse Mutation Assay)	-	-	1	CIR, 2017
Ames test, S. typhimurium (TA98, TA100, TA1535 and TA 1537) and E. coli (WP2uvrA)	-	-	-	CIR, 2017
OECD Guideline 473 (In Vitro mammalian chromosome aberration test) Chinese hamster ovary cells	-	+	1	ECHA
OECD Guideline 476 (Chinese hamster ovary cells)	-	-	1	ECHA

*+, positive; -, negative.

In Vivo Studies

An OECD Guideline 475 (Mammalian Bone Marrow Chromosome Abberation Test) study was conducted using Sprague Dawley rats exposed via oral gavage to sodium acryloyldimethyltaurate. The test material was non-clastogenic in rat bone marrow cells under the conditions of the assay (ECHA). [Kl. Score = 1]...

G. Carcinogenicity

Oral

No studies are available.

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

Oral

An OECD Guideline 421 (Reproduction / Developmental Toxicity Screening Test) was performed using male and female Sprague-Dawley rats. Dosing preparations were administered orally, by gavage, as a single dose daily to F0 males and females beginning two weeks prior to mating. The F0 males were dosed for approximately seven weeks, including two weeks prior to mating, during mating and post-mating. The F0 females were dosed throughout the study, including two weeks prior to mating, during mating, during gestation, and following parturition. Individual doses were adjusted based on the most recent body weight data. Both F0 males and females were dosed up to and including the day prior to scheduled euthanasia.

Oral administration of OS#132086 at dosage levels of 100, 500 and 1000 mg/kg/day had no effect on F0 survival, growth, mating behavior, copulation, fertility, precoital intervals, gestation lengths, corpora lutea counts, implantation counts, mean live litter size, prelpost-implantation loss, gross necropsy findings or organ weights (testes and epididymides). Histopathological examination of the testes, ovaries and epididymides from control and high-dose rats did not reveal any test article-related microscopic changes. No test article-related effects were observed in the F1 offspring with respect to survival, clinical observations, body weights or gross necropsy findings. In addition, there were no indications of test article-related developmental effects in the F1 pups at any dosage level tested. Based on the results, a dosage level of 1000 mg/kg bw/day was considered a NOEL for this reproduction and developmental screening study in rats (ECHA). [Kl. Score = 1].

I. Developmental Toxicity

No studies are available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for sodium acryloyldimethyltaurate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The developmental toxicity NOAEL of 1,000 mg/kg bw/day was determined for a test substance that contained sodium acryloyldimethyltaurate. This value is equivalent to the NOAEL determined from a repeated dose oral toxicity study for sodium acryloyldimethyltaurate (also 1,000 mg/kg bw/day). This NOAEL will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1
Oral RfD = 1000/(10 x 10 x 1 x 1 x 10 x 1) = 1000/1000 = 1 mg/kg/day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

Sodium acryloyldimethyltaurate is not considered a carcinogen. Thus, a cancer reference value will not be calculated for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium acryloyldimethyltaurate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium acryloyldimethyltaurate exhibits low toxicity to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on sodium acryloyldimethyltaurate.

Table 3: Acute Aquatic Toxicity Studies on Sodium Acryloyldimethyltaurate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Lepomis macrochirus (Bluegill)	96-hour LC_{50}	1000	1	ECHA
Daphnia magna	48-hour EC_0	1000	1	ECHA

Chronic Studies

Sodium acryloyldimethyltaurate has been evaluated for its toxicity towards the fresh water alga *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in an Alga growth inhibition test according to OECD 201 under GLP requirements. The exposure duration was 96 hours under static conditions. The NOEC growth rate determined from the study was 2000 mg/L (ECHA) [Kl. Score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for sodium acryloyldimethyltaurate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (1,000 mg/L) and *Daphnia* (1,000 mg/L). Results from chronic studies are also available for one trophic level (algae), with a NOEC of 2,000 mg/L. On the basis that the data consists of short-term studies for two trophic levels and long-term studies from one trophic level, an assessment factor of 100 has been applied to the lowest reported EC_{50} value of 1,000 mg/L for Lepomis macrochirus. Therefore, the $PNEC_{water}$ is 10 mg/L.

This value is more conservative than a PNEC derived using chronic data from the algae study (i.e., 20 mg/L).

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for sodium acryloyldimethyltaurate; these values cannot be reliably estimated using QSAR models. For example, estimated K_{oc} values using USEPA's EPISUITE vary between 10 L/K (MCI method) and 0.03155 L/kg (K_{ow} method). Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$.

PNEC soil

There are no toxicity data for soil-dwelling organisms. The K_{ow} and K_{oc} have not been experimentally derived for sodium acryloyldimethyltaurate; these values cannot be reliably estimated using QSAR models. For example, estimated K_{oc} values using USEPA's EPISUITE

vary between 10 L/K (MCI method) and 0.03155 L/kg (K_{ow} method). Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Based on the information for read-across substance sodium acryloyldimethyltaurate, the polymers in this groups are not readily biodegradable. Thus, they meet the screening criteria for persistence.

The polymers in this group are not expected to bioaccumulate because of their poor water solubility and high molecular weight. Therefore, these polymers do not meet the screening criterion for bioaccumulation.

The chronic toxicity data on read-across substance sodium acryloyldimethyltaurate show NOECs of > 0.1 mg/L. Acute $E(L)C_{50}$ values are also greater than 1 mg/L. Thus, the polymers in this group do not meet the screening criteria for toxicity.

The overall conclusion is that acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer and polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Irritation-Skin: H315 Causes skin irritation.

Aquatic Tox. H413: May cause long lasting harmful effects to aquatic life.

B. Signal word

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Please refer to the product SDS for additional information and for confirmation of the information provided herein.

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for acrylamide, 2-acrylamido-2-methylpropanesulfonic acid, sodium salt polymer or polymer of 2-acrylamido-2-methylpropanesulfonic acid sodium salt and methyl acrylate.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be an effective type of air-purifying respirator: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: none

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

CIR. (2017). Safety Assessment of Acryloyldimethyltaurate Polymers as Used in Cosmetics.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). European Centre for Ecotoxicology and Toxicology of Chemicals The Role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and the Related Food Web. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Technical Report No. 68, Brussels.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Guiney, P. D., McLaughlin, J. E., Hamilton, J. D., and Reinert, K. H. (1997). Dispersion Polymers. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs (Hamilton, J.D. and Sutcliffe, R. eds.), pp. 147-165, Van Nostrand Reinhold.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

AMMONIUM SULFATE

This dossier on ammonium sulfate (CAS RN 7783-20-2) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): diazanium sulfate

CAS RN: 7783-20-2

Molecular formula: $H_8N_2O_4S$

Molecular weight: 132.14 g/mol

Synonyms: ammonium sulfate, diammonium sulfate, sulfuric acid diammonium salt, mascagnite

SMILES: [NH4+].[NH4+].[O-]S(=O)(=O)[O-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-chemical Properties of Ammonium Sulfate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	solid	2	ECHA
Melting Point	> 280°C (pressure not provided)	2	ECHA
Boiling Point	Not applicable as substance is solid	1	ECHA
Density	1770 kg/m^3 @ 25°C	2	ECHA
Vapour Pressure	0 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-5.1 @ 25°C	2	ECHA
Water Solubility	767 g/L @ 25°C	2	ECHA
Flash Point	Not applicable as substance is solid	1	ECHA
Auto flammability	Not applicable as substance is solid	1	ECHA
Viscosity	Not applicable as substance is solid	1	ECHA
Dissociation constant (pKa)	9.25 @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Ammonium sulfate dissociates in aqueous media to the ammonium ion (NH_4^+) and sulfate anion (SO_4^{2-}). Ammonium sulfate is an inorganic ionic substance that is not expected to adsorb or bioaccumulate. Ammonium sulfate is hydrophilic, and it has high mobility in the soil.

B. Biodegradation

Given the fact the ammonium sulfate is an inorganic substance, biodegradation testing is not applicable.

C. Environmental Distribution

Ammonium sulfate is water soluble so it is mainly expected to partition to aqueous phase. Based on its log K_{ow}, it is not expected to adsorb substantially to the soil phase.

D. Bioaccumulation

No experimental data were available for bioaccumulation or bioconcentration of ammonium sulfate. Based on the high water solubility and the ionic nature, ammonium sulfate is not expected to adsorb or bioaccumulate to a significant extent. In addition, due to the log K_{ow} of –5.1 bioaccumulation is not expected (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Ammonium sulfate exhibits low acute toxicity by the oral, inhalation and dermal routes. It is not irritating to the skin and eyes; and it is not a skin sensitiser. In repeated dose toxicity studies, dose-related changes were not observed in rats given ammonium sulfate in feed for 52-weeks. Ammonium sulfate is not genotoxic and is not carcinogenic. No reproductive or developmental effects were observed in read-across studies.

B. Acute Toxicity

<u>Oral</u>

In an OECD Guideline (401) study, Gassner rats were exposed to ammonium sulfate via oral gavage. The LD_{50} was determined to be 4,250 mg/kg bw/day in male and female rats (ECHA) [KI score = 2].

In an OECD Guideline (423 Acute Oral Toxicity) study Wistar rats were exposed to ammonium sulfate via oral gavage. The LD_{50} in rats was determined to be > 2000 mg/kg bw/day (ECHA) [KI score = 2].

<u>Inhalation</u>

In an OECD Guideline 433 (Acute Inhalation Toxicity: Fixed Concentration Procedure) study Sprague-Dawley rats were exposed to ammonium sulfate via nose only aerosol inhalation.

The resulting LC_0 was determined to be 3.5 mg/m^3 after 4 hours of exposure (ECHA) [KI score = 2].

Dermal

In an OECD Guideline 434 (Acute Dermal Toxicity) study Wistar rats were exposed to ammonium sulfate via open coverage. The LD50 for this study was determined to be > 2000 mg/kg bw/day (ECHA) [KI score = 2].

C. Irritation

Skin

Vienna White rabbits were exposed to ammonium sulfate for up to 20 hours and they were observed for 8 days. There were no signs of clinical toxicity, so ammonium sulfate is not considered irritating to the skin (ECHA) [KI score = 2].

Eye

Ammonium sulfate was placed on the eyes of Vienna White rabbits without rinsing for 8 days. All of the observed effects were considered reversible, so this substance is not considered an eye irritant (ECHA) [KI score 2].

D. Sensitisation

A guinea pig maximisation test was used to determine if ammonium sulfate is a skin sensitiser. The animals did not show any signs of toxicity throughout the study period. [KI. score = 1]. Ammonium sulfate is not sensitising to the skin of guinea pigs (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

In an OECD 453 (Combined Chronic Toxicity/Carcinogenicity) study Fischer 344 rats were continuously exposed to ammonium sulfate via their feed for 52weeks.

In the chronic study, groups of 10 rats/sex were fed a diet containing the test substance (purity not given) at concentrations of 0, 0.1, 0.6, or 3% for 1 year. These concentrations corresponded to average daily intakes of 0, 42, 256, and 1527 mg/kg bw/day for males and 0, 48, 284, and 1490 mg/kg bw/day for females, respectively.

No mortality was found in any groups throughout the treatment period. No test substance-related change in the body weights was found. Absolute and relative kidney weights were increased at the high dose level for both sexes. Absolute spleen weights were decreased and relative liver weights were increased in high dose males. No dose-related changes were found in the other organs.

The NOAEL for females was determined to be 284 mg/kg bw/day and the NOAEL for males was determined to be 256 mg/kg bw/day (ECHA) [KI score = 1].

Inhalation

Rats were exposed via whole body inhalation of ammonium sulfate for 8 hours a day over a 14-day treatment period. The NOEC was determined to be 300 mg/m^3 (ECHA) [KI score = 2].

Dermal

No data were available**.**

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on ammonium sulfate based are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Ammonium Sulfate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100	-	-	2	ECHA
OECD Guidline 476 (In vitro Mammalian Cell Gene Mutation Test) Chinese hamster lung fibroblasts (V79)	-	-	1	ECHA
OECD Guidline 473 (In vitro Mammalian Chromosome Aberration Test) human lymphocytes	-	-	2	ECHA

*+, positive; -, negative.

In Vivo Studies

An *in vivo* mammalian somatic cell study also known as the cytogenicity/erythrocyte micronucleus cell test was conducted using ddY mice exposed to ammonium sulfate. The results showed that ammonium sulfate is not genotoxic to mice as there were no adverse effects observed (ECHA) [KI score = 2].

G. Carcinogenicity

Oral

A chronic oral toxicity and carcinogenicity study was conducted in rats, similar to the requirements of OECD TG 453. For investigation of the carcinogenic potential, groups of 50 rats/sex were fed a diet containing the test substance (purity not given) at concentrations of 0, 1.5, or 3% for 2 years. These concentrations corresponded to average daily intakes of 0, 564.1, and 1288.2 mg/kg bw/day for males and 0, 4649.9, and 1371.4 mg/kg bw/day for females respectively.

No macroscopic changes were recorded by gross pathology, except for massive nodular or focal lesions suggesting neoplastic changes. At histopathological examination, non-neoplastic and neoplastic lesions were noted in the control and treatment groups, with no significant inter-group difference in their incidences or severity.

The authors concluded that the no observed adverse effect level of ammonium sulfate was the 0.6% diet, which is equivalent to 256 and 284 mg/kg bw/d in males and females, respectively, and the compound is noncarcinogenic under the conditions of the study. There was no evidence of a long-term carcinogenic activity of the test substance.

Data on purity of the test substance are lacking; however, since no adverse effects were observed, this is not considered to affect the evaluation of the carcinogenic potential of ammonium sulfate in an adverse manner (ECHA) [Kl. Score = 1].

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

Oral

Read across of data for ammonium phosphate (7783-28-0) was conducted to screen for the reproductive and developmental toxicity effects of ammonium sulfate. A one generation reproductive toxicity study was conducted using Sprague Dawley rats exposed via oral gavage. The NOAEL for reproductive toxicity was determined to be 1500 mg/kg bw/day (ECHA) [KI score = 1].

I. Developmental Toxicity

An OECD Guideline 422 (Combined Repeated Dose Toxicity) study was conducted using Sprague Dawley rats exposed via oral gavage to a read across substance, ammonium phosphate (7783-28-0), for two weeks. A NOAEL could not be established for maternal toxicity based on inflammatory/degenerative stomach changes recorded during histopathological examination. The foetal NOAEL was determined to be 1,500 mg/kg bw/day (ECHA) [Kl. Score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ammonium sulfate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

Oral

The NOAEL from a rat 52-week oral feeding study was reported to be 256 mg/kg bw/day for males based on the actual dose received. This NOAEL will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 256/(10 x 10 x 1 x 1 x 1) = 256/100 = 2.56 mg/kg/day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (2.56 x 70 x 0.1)/2 = 8.96 mg/L

B. Cancer

Ammonium sulfate is not considered a carcinogen. Thus, a cancer reference value will not be calculated for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ammonium does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ammonium sulfate is of low acute concern to aquatic life. Algae is more tolerant than fish or invertebrates.

B. Aquatic Toxicity

In aqueous solution, ammonium salts are completely dissociated into NH_4^+ and a corresponding anion. This equilibrium depends on temperature, pH and ionic strength of the water in the environment. Un-ionized NH_3 species exists in the aquatic environments and the fraction (NH_3/(NH_3 +NH_4^+)) steeply increases with elevated pH value or temperature. It is well known that toxicity to aquatic organisms has been attributed to un-ionized ammonia (NH_3) species, and NH_4^+ species is considered to be non- or significantly less-toxic (Emerson et al., 1975 in ECHA). However, recent developments in assessing ammonia toxicity clearly show that in contrast to earlier assumptions where un-ionized ammonia was considered to be the toxic component, both the uncharged and charged molecule are toxic. Therefore, a joint toxicity model has been proposed, with ammonia causing most toxicity at high pH values and ammonium ion also contributing to toxicity at lower pH values (U.S. EPA 1999, OECD 2007 in ECHA).

It is generally accepted, that the principal toxic component of ammonium salts such as ammonium chloride or -sulphate is ammonia, rather than the corresponding anion (see also: OECD 2004, SIDS ammonium chloride or OECD 2007 ammonium sulphate). Therefore, toxicity values for ammonium salts (such as: ammonium -sulphates, phosphates, carbonates, chlorides or nitrates), where the major toxic component is ammonia, can be considered as equivalent, therefore read-across to those substances is possible. Consequently, the aquatic toxicity data compiled for ammonium sulfate comprises the total topic of ammonia toxicity. Species mean chronic values (SMCV) as described in ECHA were considered as relevant endpoints.

<u>Acute Studies</u>

Table 3 lists the results of acute aquatic toxicity studies conducted on ammonium sulfate.

Table 3: Acute Aquatic Toxicity Studies on Ammonium Sulfate[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Onchorhyncus mykiss, Salmo gairdneri	96-hour LC_{50} mortality	53	1	ECHA
Prosopium williamsoni	96-hour LC_{50}	57.2	1	ECHA
Ceriodaphnia acanthina	48-hour EC_{50} mobility	121.7	1	ECHA
Daphnia magna	48-hour EC_{50} mobility	169	1	ECHA

1 - Acute toxicity results were normalized to pH 8 and ammonium sulfate.

Chronic Studies

Chronic values were normalized to 25°C. As indicated, plants (algae) are more tolerant than fish or invertebrates to ammonia.

Fish: A 30-day study was conducted to determine the toxicity of ammonium sulfate to *Lepomis macrochirus.* The EC_{10} for ammonium sulfate was determined to be 5.29 mg/L (ECHA) [KI score 1].

Invertebrates: A 10-week study was conducted to determine the toxicity ammonium sulfate to *Hyallella azteca*. The EC_{10} for ammonium sulfate was determined to be 3.12 mg/L based on reproduction (ECHA) [KI score = 1].

Algae: An 18-day study was conducted to determine the toxicity of ammonium sulfate to *Chlorella vulgaris*. The EC_{50} value for ammonium sulfate was determined to be 2,700 mg/L (ECHA) [KI score = 2].

A 5-day study was conducted to determine the toxicity of ammonium sulfate to *Chlorella vulgaris*. The EC_{50} value for ammonium sulfate was determined to be 1,605 mg/L based on the growth rate (ECHA) [KI. Score = 2].

C. Terrestrial Toxicity

No reliable studies available.

D. Calculation of PNEC

The PNEC calculations for ammonium sulfate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (53 mg/L) and invertebrates (121.7 mg/L). NOEC values from long-term studies are available for fish (5.29 mg/L), invertebrates (3.12 mg/L) and algae (1,605 mg/L). On the basis that the data consists of short-term results from two trophic levels and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported EC_{10} value of 3.12 mg/L for invertebrates. Therefore, the $PNEC_{water}$ is 0.312 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Ammonium sulfate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as ammonium sulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on its properties, no adsorption of ammonium sulfate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of ammonium sulfate is dominated by its water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as ammonium sulfate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, ammonium sulfate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ammonium sulfate is an inorganic salt that dissociates completely to ammonium and sulfate ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to ammonium sulfate or its dissociated ions.

The estimated log K_{ow} is for ammonium sulfate is equal to -5.1. This value suggests that ammonium sulfate is not expected to bioaccumulate (ECETOC, 2000). Therefore, ammonium sulfate does not meet the screening criterion for bioaccumulation.

The NOEC or EC10 values from chronic aquatic toxicity studies are > 0.1 mg/L. The acute $E(L)C_{50}$ values for fish and invertebrates are > 1 mg/L. Thus, ammonium sulfate does not meet the criteria for toxicity.

The overall conclusion is that ammonium sulfate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity: H302: Harmful if swallowed

Irritation: H315: Causes skin irritation

Eye: H318: Cause serious eye damage

STOT: H335: May cause respiratory irritation

B. Signal word

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ammonium sulfate.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: 20506 (Solid). This UN number is for ammonium hydrogen sulfate.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). European Centre for Ecotoxicology and Toxicology of Chemicals The Role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and the Related Food Web. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Technical Report No. 68, Brussels.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

BUT-2-ENEDIOIC ACID (FUMARIC ACID)

This dossier on but-2-enedioic acid (fumaric acid) presents the most critical studies pertinent to the risk assessment of this substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2E)-but-2-enedioic acid

CAS RN: 110-17-8

Molecular formula: $C_4H_4O_4$

Molecular weight: 116.07 g/mol

Synonyms: fumaric acid, 2-Butenedioic acid, trans-Butenedioic acid, Allomaleic acid, Boletic acid, (2E)-but-2-enedioic acid, Lichenic acid

SMILES: C(=CC(=O)O)C(=O)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of But-2-enedioc Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless crystalline solid	2	ECHA
Melting Point	287°C @ 101.3 kPa	2	ECHA
Boiling Point	Sublimes at 200°C; @ 0.23 kPa, fumaric acid sublimes at 165°C	2	ECHA
Density	1640 kg/m^3 at 20°C	2	ECHA
Vapour Pressure	0.02 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-4.02 @ 20°C (Experimental)	2	ECHA
Water Solubility	7 g/L @ 25°C	2	ECHA
Flash Point	Flash point is only relevant to liquids and low melting point solids	2	ECHA
Auto flammability	399°C	2	ECHA
Viscosity	Not applicable as substance is a solid	2	ECHA
Dissociation constant	K1 = 9.3 x 10^{-4} at 25°C K2 = 2.9 x 10^{-5} at 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Fumaric acid is readily biodegradable, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Partitioning

The pKa of fumaric acid is 3.03 and 4.54, indicating that this substance will exist partially in anion form in the environment and anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterparts (PubChem).

Volatilisation of fumaric acid from moist soil surfaces is not expected to be an important fate process because the acid exists as an anion and anions do not volatilise (PubChem).

Hydrolysis is not expected to be an important environmental fate process since this substance lacks functional groups that hydrolyse under environmental conditions (PubChem).

C. Biodegradation

The ready biodegradability of fumaric acid was determined using the OECD 301B guideline in a GLP study.

Using a non-adapted sludge from a domestic source, the percentage of biodegradation observed comprised 60.1% after 11 days (i.e., within the 10-day window) and 67.5% after 28 days. The reference substance (sodium benzoate) incubated under the same conditions showed a percentage biodegradation of 60.1% after 11 days. Incubation of the test substance and the reference substance demonstrated that the test substance did not significantly inhibit the microbial activity of the activated sludge.

Accordingly, fumaric acid is considered readily biodegradable [KI score = 1]. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

No experimental data are available for fumaric acid. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} values from the molecular connectivity index (MCI) is 0.865 L/kg. Thus, fumaric acid has a low potential for adsorption to soil and is expected to have very high mobility. Likewise, based on these values along with fumaric acid's high water solubility, if released to water, it will likely not adsorb to suspended solids or sediments.

E. Bioaccumulation

There are no bioaccumulation studies on fumaric acid. The substance has a low potential for bioaccumulation based on log $K_{ow} \leq 3$.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Fumaric acid is an organic dicarboxylic acid and is naturally found in plants and animals. Fumaric acid is approved for use as a food additive in Australia and use as a therapeutic agent in the treatment of psoriasis and other skin disorders, as wells as a feed additive for all animals without a maximum level. Dietary exposure results from the large volumes of fumaric acid used as a food acidulant in applications such as beverages, baking powders and fruit drinks. The Joint FAO/WHO Committee on Food Additives and Contaminants (JECFA, 1999) concluded that there is no safety concern at current levels of intake when used as a flavouring agent (ECHA).

Fumaric acid has low acute toxicity via oral, inhalation or dermal exposure and was practically nontoxic when tested in guideline-comparable studies of acute oral and acute dermal toxicity.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was conducted using male and female Sprague Dawley rats. The substance was administered orally via gavage. The LD_{50} values for the oral administration of fumaric acid in rats range from 9,300 (female rats) to 10,700 mg/kg bw (male rats) (ECHA) [KI Score = 1].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was conducted using female New Zealand white rabbits. Single dose dermal toxicity of fumaric acid using female New Zealand albino rabbits was reported as 20,000 mg/kg (ECHA) [KI Score = 1].

Inhalation

An OECD Guideline 403 (Acute Inhalation Toxicity) was undertaken. An inhalation LD_{50} for rats is reported to be 1,306 mg/L (ECHA) [KI Score = 1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted using small white Russian male and female rabbits. Dermal application of 0.5 g fumaric acid was mildly irritating to the skin of male and female rabbits. Fumaric acid did not elicit dermal reactions that would exceed the threshold for classification in accordance with EU criteria (ECHA) [KI Score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) was undertaken where test material was applied to the lower conjunctival sac of the right eye by pulling away the lower

eyelid. The left eye was treated in one animal. The contralateral eye served as a concurrent, inherent control.

Application of 0.1 g fumaric acid to the eyes of male and female rabbits was considered irritating to the eye and ocular mucous membrane. Fumaric acid is classified as an eye irritant (ECHA) [KI Score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) guinea pig maximisation test was conducted. Fumaric acid shows no sensitisation effect on the skin of female guinea pigs according to the Magnusson-Kligman maximisation test. Fumaric acid is not considered a skin sensitiser.

E. Repeat Dose Toxicity

A Peer-reviewed study comparable to OECD guideline 452 was conducted using male Osborne-Mendel rats over a two-year period.

In a two-year dietary study using male rats, a very slight increase in mortality rate and some testicular atrophy was observed after administration of 1.5% fumaric acid (approximately 750 mg/kg bw/day). Gross and microscopic examination of major organs revealed no abnormalities. The authors of this study concluded that inanition was partly responsible for testicular atrophy. A previous study conducted in a similar manner with female rats showed no adverse effects on reproductive organs after administration of up to 1.2% fumaric acid in the diet for 2 years. Based on the low incidence of mortality of male rats, 1.2% is very near a NOAEL for chronic exposure to fumaric acid (600 mg/kg bw/day). The 1.2% NOAEL (600 mg/kg bw/day) derived from the available long-term rat toxicity data was confirmed as the appropriate point of departure. No non-neoplastic or neoplastic effects were noted supporting the conclusion that the substance is not a carcinogen (ECHA) [KI Score = 2].

F. Genotoxicity

An OECD Guideline 476 (*In Vitro* Mammalian Cell Gene Mutation Test) was performed using mouse lymphoma L5178Y cells. Under the experimental conditions reported, fumaric acid did not induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation. Thus, fumaric acid is not considered to be a mutagen.

G. Carcinogenicity

Fumaric acid is not considered to be a carcinogen and is not classified as such by the International Agency for Research on Cancer (IARC) or the United States Environment Protection Agency (USEPA). In agreement with the regulatory agency, the two-year repeated dose toxicity testing discussed above showed no carcinogenic effects.

H. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed using male and female Charles River CD rats. Substance was administered orally via gavage in a corn oil vehicle at dosage levels of 20, 55 and 150 mg/kg/day.

In a multigeneration reproduction study (similar to OECD guideline 416) maleic anhydride (purity 99%) was administered to 10 male and 20 female rats/dose by gavage at dose levels of 0, 20, 55 and 150 mg/kg bw/day. The rats were mated to produce two generations, each with two litters. Groups of the same size from the second litter were used for subsequent generations and were given the same dose of maleic anhydride as were their parents. Since 100% mortality was observed among parental F1 female rats at 150 mg/kg bw/day, the high dose group was terminated in the F1 generation, and a parental systemic NOAEL of 55 mg/kg bw/day was the highest dose tested in the F1 generation. The study was reduced from a three-generation to a two-generation study.

Renal cortical necrosis occurred in high-dose P/F0 males and females. Increased kidney weights were observed in low- and mid-dose adult F1 females. Therefore, no NOAEL could be determined, and the LOAEL (systemic) was regarded as 20 mg/kg bw/day. With respect to fertility, neither a dose-related reduction nor a pattern (during the two consecutive matings) within the parental (P0) generation suggested a treatment-related effect. No adverse effects on fertility were observed. Based on these observations the NOAEL (fertility) was derived at 55 mg/kg bw/day (highest dose tested under the conditions of this study) (ECHA) [Kl Score = 1].

I. Developmental Toxicity

A peer reviewed dietary study was conducted on an unspecified strain of rat.

Rats were fed 1,000 or 10,000 ppm malic acid, a metabolite of fumaric acid, for 9 weeks prior to mating. One week after weaning of the last F1A litter, the P1 parents were remated to produce the F1B litter. Ten male and 20 female weanlings from each dose group were selected for the P2 generation and administered the appropriate diets. The animals were mated at 100 days of age to produce the F2A generation. One week after weaning of the F2A litter, the P2 parents were remated to produce the F2B litter.

Maternal Effects: Body weight gain of female animals was comparable to controls prior to mating. Body weight gains of male animals in test groups were slightly decreased compared to controls. Feed consumption, survival, appearance and behaviour were similar for P1 test and control rats. The P2 test and control animals were similar throughout the study and wheezing was observed in all groups during the F2B phase. A NOAEL for maternal systemic toxicity was determined to be > 10, 000 mg/kg/day.

Foetal Effects: The F2B generation showed no meaningful differences between test and control animals in the number and placement of implantation and resorption sites or in the number, weight or length of live neonates; none of the neonates died. The skeletal development of F2B neonates was similar between test and control animals. Slight differences in developmental indices were considered to be within the range of normal variations in foetal development and no trend toward lesser or greater skeletal development was observed (ECHA) [Kl Score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for fumaric acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021)

A. Non-Cancer

Oral

The repeated dose NOAEL for fumaric acid is 600 mg/kg/day and will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 600/100 = 6 mg/kg/day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (6 x 70 x 0.1)/2 = 21 mg/L

B. Cancer

The substance is not considered a carcinogen. Thus, a cancer reference value will not be calculated.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Fumaric acid does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Fumaric acid is of low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 presents the results of acute aquatic toxicity studies on fumaric acid.

Table 2: Acute Aquatic Toxicity Studies on Fumaric Acid

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Danio rerio	96-hour LC_{50}	> 100	1	ECHA
Daphnia magna	48-hour EC_{50}	> 100	1	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	> 100	1	ECHA

Chronic Studies

No data are available.

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

The PNEC calculations for the substance follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (> 100 mg/L), *Daphnia* (> 100 mg/L) and algae (> 100 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported NOEC of 100 mg/L for algae. The $PNEC_{water}$ is 1 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.637 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.8166/1280) \times 1000 \times 1$
$= 0.637$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.0346/1000 \times 2400]$
$= 0.8166\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= -0.865 \times 0.04$
$= 0.03460$ L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg) presented above as 0.865 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.0115 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.0173/1500) \times 1000 \times 1$
$= 0.0115$ mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
$= 0.865 \times 0.02$
$= 0.0173\ m^3/m^3$

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg) presented above as 0.865 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Fumaric acid is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Bioaccumulation of fumaric acid is not expected to occur based on it log K_{ow} value of -4.02 (Table 1). Thus, fumaric acid does not meet the screening criteria for bioaccumulation.

No chronic aquatic toxicity data exist on fumaric acid; however, the acute E(L)C_{50} values are > 1 mg/L in fish, invertebrates and algae. Therefore, fumaric acid does not meet the screening criteria for toxicity.

Therefore, fumaric acid is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H319: Causes serious eye irritation.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention if symptoms persist.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Get medical attention if symptoms persist.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray, powder or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours, or spray Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Pick up mechanically. If formation of dust cannot be avoided use respiratory filter device. Dispose of the material collected according to regulations.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for but-2-enedioic acid.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

But-2-enedioic acid is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 1999. Fumaric acid. Summary of evaluations performed by the Joint FAO/WHO Expert Committee on Food Additives.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

PubChem. https://pubchem.ncbi.nlm.nih.gov/compound/Fumaric-acid#section=Computed-Descriptors. Accessed January 2022.

U.S. Environmental Protection Agency [EPA]. (2017). EPI Suite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

CALCIUM CHLORIDE

This dossier on calcium chloride presents the most critical studies pertinent to the risk assessment of calcium chloride in its use as use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA) and the OECD-SIDS documents on calcium chloride (OECD, 2002). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Calcium dichloride

CAS RN: 10043-52-4

Molecular formula: $CaCl_2$

Molecular weight: 110.98 g/mol

Synonyms: Calcium chloride; calcium dichloride; calcium chloride anhydrous

SMILES: Cl(Ca)Cl

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Calcium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White odourless solid; crystals; powder; or granules	2	ECHA
Melting Point	782°C @ 101.3 kPa	2	ECHA
Boiling Point	> 1,600°C @ 101.3 kPa	2	ECHA
Density	2150 kg/m^3 @ 25°C	2	ECHA
Vapour Pressure	-	-	-
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	745 g/L @ 20°C (very soluble)	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Calcium chloride dissociates completely in aqueous solutions to calcium (Ca^{2+}) and chloride (Cl^-) ions. Calcium chloride and its dissociated ions are ubiquitous in the environment.

Because of its dissociation properties and high water solubility, calcium chloride is not expected to be adsorbed to soil. The calcium ion may bind to soil particulate or may form stable inorganic salts with sulfate and carbonate ions. The chloride ion is mobile in soil and eventually drains into the surface water because it is readily dissolved in water (OECD, 2002).

Calcium (Ca^{2+}) and chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (Ganong, 1995). Neither calcium chloride nor its dissociated ions are expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Calcium chloride exhibits low acute toxicity by the oral and dermal routes. It is irritating to the eyes, but not to the skin. There was no toxicity or carcinogenic effects in rats given calcium chloride in the diet for 12 months. Calcium chloride is not genotoxic. No developmental toxicity was reported in pregnant female rats, mice or rabbits given oral doses of calcium chloride.

B. Acute Toxicity

The oral LD_{50} values in rats are 2,301, 4,179 and 3,798 mg/kg (ECHA) [KI score = 2]. The dermal LD_{50} in rabbits is > 5,000 mg/kg (ECHA) [KI score = 1].

C. Irritation

Application of 0.5 mL to the skin of rabbits for 4 hours under occlusive conditions was non-irritating. Erythema and edema scores at all time points were zero (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was moderately irritating. The mean of the 24, 48 and 72-hour scores were: 0.67 for conjunctival redness; 0.78 for chemosis; 1.0 for corneal opacity; and 0.0 for iridial lesions. There were no signs of irritation by Day 21 (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was highly irritating. The mean of the 24, 48 and 72-hour scores were: 1.9 for conjunctival redness; 2.2 for chemosis; 2.0 for corneal opacity; and 1.0 for iridial lesions. The effects were not fully reversible by Day 21 (ECHA) [KI score = 1].

Instillation of 100 mg of calcium chloride into the eyes of rabbits was irritating. The mean of the 24, 48 and 72-hour scores were: 1.54 for conjunctival redness; 1.65 for chemosis; 1.0 for corneal opacity; and 0.33 for iridial lesions. The effects were not fully reversible by Day 21 (ECHA) [KI score = 2].

D. Sensitisation

No reliable studies are available.

E. Repeated Dose Toxicity

<u>Oral</u>

Rats were fed a 20 mg calcium chloride/g body weight diet for 12 months. There were no differences in mortality, weight gain or feed consumption between treated and control groups. No neoplastic lesions were observed in the gastrointestinal tract, urinary tract, liver, heart, brain or spleen. The estimated daily intake of calcium chloride is 1,000 to 2,000 mg/kg/day (OECD, 2002) [KI score = 3].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on calcium chloride are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Calcium Chloride

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium*)	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium*)	-	-	2	ECHA
Chromosomal aberration (Chinese hamster lung cells)	-	NC	2	ECHA

*+, positive; -, negative; NC, not conducted.

In Vivo Studies

No studies are available.

G. Carcinogenicity

Rats were fed 20 mg calcium chloride/g diet for 12 months. There were no differences in mortality, weight gain or feed consumption between treated and control groups. No neoplastic lesions were observed in the gastrointestinal tract, urinary tract, liver, heart, brain or spleen. The estimated daily intake of calcium chloride is 1,000 to 2,000 mg/kg/day (OECD, 2002) [Kl score = 3].

H. Reproductive Toxicity

No studies are available.

I. Developmental Toxicity

Pregnant female Wistar rats were dosed by oral gavage with 0, 1.76, 8.18, 38 or 176 mg/kg calcium chloride on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 176 mg/kg/day (ECHA) [Kl score = 1].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 1.89, 8.78, 40.8 or 189 mg/kg calcium chloride on GD 6-15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 189 mg/kg/day (ECHA) [Kl score = 1].

Pregnant female Dutch rabbits were dosed by oral gavage with 0, 1.69, 7.85, 35.6 or 169 mg/kg calcium chloride on GD 6-18. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 169 mg/kg/day (ECHA) [KI score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived from calcium chloride.

Calcium chloride dissociates in water to calcium and chloride ions. An Australian drinking water guidance value is not available for calcium (ADWG, 2021). The Australian drinking water guidance value for chloride is 250 mg/L based on aesthetics (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Calcium chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Calcium chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on calcium chloride.

Table 3: Acute Aquatic Toxicity Studies on Calcium Chloride

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	4,630	2	OECD, 2002; ECHA
Lepomis macrochirus	96-hour LC_{50}	9,500-11,300	2	OECD, 2002; ECHA
Gambusia affinis	96-hour LC_{50}	13,400	2	OECD, 2002; ECHA
Lepomis macrochirus	96-hour LC_{50}	10,650	2	OECD 2002; ECHA
Daphnia magna	48-hour EC_{50}	2,400	1	OECD, 2002; ECHA
Daphnia magna	48-hour EC_{50}	2,770	2	OECD, 2002; ECHA
Ceriodaphnia dubia	48-hour EC_{50}	1,830	2	OECD, 2002; ECHA
Daphnia magna	48-hour EC_{50}	1,062	2	OECD, 2002; ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	2,900 (biomass)	1	OECD, 2002; ECHA

Chronic Studies

The 21-day EC_{50} and EC_{16} values for calcium chloride in a chronic *Daphnia* reproduction study were 610 and 320 mg/L, respectively (OECD, 2002).

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for calcium chloride follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (4,630 mg/L), invertebrates (1,062 mg/L) and algae (2,900 mg/L). Although a chronic *Daphnia* study is available, an NOEC or EC_{10} was not determined. On the basis that the data consist of short-term and long-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported acute EC_{50} value of 1,062 mg/L from invertebrates. The $PNEC_{water}$ is 11 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. Calcium chloride is highly soluble and dissociates completely in water. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as calcium chloride. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of calcium chloride to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. Calcium chloride dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as calcium chloride. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, no adsorption of calcium chloride to the soil is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Calcium chloride is an inorganic salt that dissociates completely to calcium and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both calcium and chloride ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Calcium and chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Thus, calcium chloride is not expected to bioaccumulate.

A chronic toxicity has been conducted on calcium chloride, but an NOEC or EC_{10} was not determined. The acute E(L)C_{50} values for calcium chloride are > 1 mg/L in fish, invertebrates and algae. Thus, calcium chloride does not meet the screening criteria for toxicity.

The overall conclusion is that calcium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Eye Irritant Category 2

[Note: anhydrous calcium chloride requires the GHS classification Eye Irritant Category 1]

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on the conditions, decomposition products may include the following: hydrogen chloride gas, calcium oxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessarily provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for calcium chloride.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Calcium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD (2002). OECD-SIDS: Calcium chloride (CAS No. 10043-52-4), UNEP Publications. Available at: https://hpvchemicals.oecd.org/UI/handler.axd?id=cb4247c6-7f28-4ca5-bf69-1f526956b6f9

CHOLINE CHLORIDE

This dossier on choline chloride (CAS RN 67-48-1) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on choline chloride (OECD, 2004), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-hydroxy-N,N,N-trimethylethanaminium chloride

CAS RN: 67-48-1

Molecular formula: $C_5H_{14}NO.Cl$

Molecular weight: 139.6 g/mol

Synonyms: Choline chloride; 2-hydroxy-N,N,N-trimethylethanaminium chloride; trimethyl(2-hydroxyethyl)ammonium chloride; cholinium chloride; 2-hydroxyethyl(trimethyl)azanium chloride

SMILES: C[N+](C)(C)CCO.[Cl-]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Choline Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	White crystalline solid*	2	OECD (2004)
Melting Point	~ 200°C @ 101.3 kPa	1	ECHA
Boiling Point	Decomposition at 305°C @ 101.3 kPa prior to boiling	2	ECHA
Density	70% aq. solution: 1110 kg/m^3@ 20°C	4	OECD (2004)
Partition Coefficient (log K_{ow})	75% aq. solution: -3.77 @ 25°C	1	ECHA
Vapour Pressure	2287.2 Pa @ 25°C (QSAR)	2	ECHA
Water Solubility	Powder containing 50% choline chloride: 650 g/L (temperature unknown	4	OECD (2004)
Auto flammability	330°C	2	ECHA

Property	Value	Klimisch score	Reference
Viscosity	75% aq. solution: 26.2 mPa.s @ 20°C; 14.1 mPa.s @ 40°C	1	ECHA
Henry's Law Constant	2.06 x 10-11 Pa.m^3/mol @ 25 °C (estimated using HENRYWIN v3.10)	-	OECD (2004)

*Choline chloride is a white crystalline solid; it is marketed as an aqueous solution (70-75% w/w in water), which is colourless with an amine-like odour.

Choline chloride is a quaternary amine salt that will dissociate in water into choline ($C_5H_{14}NO^+$) ions and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

A. Partitioning

Choline chloride is highly water soluble and non-volatile. When released to water under typical environmental conditions, the quaternary ammonium salt dissociates to release a positively charged choline ion and a negatively charged chloride ion (OECD, 2004). It is unlikely to partition to the atmosphere based on its low volatility (OECD, 2004).

B. Biodegradation

Choline chloride is readily biodegradable (93% within 14 days) in a MITI-I test (MITI, 1992; OECD, 2004). In another MITI-I test, biodegradation was $\geq$60%, indicating ready biodegradation (Tunkel *et al.*, 2000; OECD, 2004). A $BOD_5/ThOD_5$ ratio of 75% was obtained in a BOD_5 test performed according to DIN 38409 part 43 (BASF AG, 1984; OECD, 2004).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

No experimental data are available for choline. Choline is a quaternary ammonium compound (QAC); these compounds are not included in the training set for the K_{oc} estimation of the QSAR model KOCWIN v. 2.00 in EPISuite™ (USEPA, 2016), and therefore outside the program's prediction domain. A K_{oc} value of 2.3 had been estimated using the older QSAR model PCKOCWIN v. 1.66 (OECD, 2004), indicating a low potential for soil adsorption.

Results from Mackay Level I modelling indicate that choline chloride will be distributed completely into water (OECD, 2004).

D. Bioaccumulation

No measured data on bioaccumulation of choline chloride is available. An experimental log K_{ow} is -3.77, which indicates a low potential to accumulate in organisms (OECD, 2004). Bioaccumulation is not expected in aquatic organisms.

E. Summary

Choline chloride is readily biodegradable. Distribution modelling using Mackay Level 1 shows choline to be distributed completely into water. Choline chloride will not adsorb on soil and sediments. It is not expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Choline is a vitamin-like essential nutrient. It has low acute toxicity by the oral route and is slightly irritating to the skin and eyes. Repeated high intake of choline in humans has been reported to cause a slight hypotensive effect. No adverse effects (including tumours) were seen in rats given choline in the diet for 72 weeks. Choline is not genotoxic. High dietary doses of choline to pregnant mice resulted in developmental toxicity (but no teratogenic effects) at levels that were maternally toxic.

NICNAS has assessed fumaric acid in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Metabolism

Choline is a vitamin-like essential nutrient. Although the body can synthesise choline in small amounts, it is insufficient to maintain health and must be consumed in the diet. Choline is required for the synthesis of phospholipids in cell membranes, methyl group metabolism and acetylcholine synthesis (neurotransmitter) (Zeisel and Blusztajn, 1994).

Dietary choline is taken up into the body by transporter proteins present in the cells lining the small intestine (IOM, 2000). In the small intestine, prior to uptake into the small intestinal cells, some choline is metabolised by bacteria to betaine and methylamines (Zeisel et al., 1980). Dietary choline can be present as free choline or in esterified forms (i.e., phosphocholine, glycerophosphocholine, sphingomyelin, and phosphatidylcholine) (Zeisel and Blusztain, 1994). Free choline is formed from these esterified choline compounds by pancreatic enzymes.

Choline is involved in a number of biochemical pathways in eukaryotic and prokaryotic cells. It is a precursor for acetylcholine (a neurotransmitter); phospholipids (structural integrity and signaling roles for cell membranes); and a major source for methyl groups (IOM, 2000).

C. Acute Toxicity

<u>Oral</u>

The oral LD_{50} values of choline in rats are approximately 3,500 and 5,500 mg/kg (ECHA) [Kl. scores = 2].

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 110-17-8%2C+

Inhalation

No acute inhalation or dermal toxicity studies are available.

D. Irritation

Skin

Application of a 70% aqueous solution to the skin of rabbits for 20 hours under occlusive conditions resulted in ambiguous skin irritation (BASF AG, 1963a; OECD, 2004) [Kl. score = 2].

Eye

Slight eye irritation was seen in the eyes of rabbits after instillation of a 70% aqueous solution of choline chloride; no effects were seen 24 hours after exposure (BASF AG, 1963b; OECD, 2004) [Kl. score = 2].

E. Sensitisation

No data are available in animals. In a Human Repeated Insult Patch Test (HRIPT), there was no evidence of dermal sensitisation in 200 subjects given 0.5% (w/v) aqueous solution of choline chloride during the induction phase and 0.2% (w/v) aqueous solution during the challenge phase (Colgate-Palmolive, 2003; OECD, 2004).

F. Repeated Dose Toxicity

Oral

A 72-week feeding study was conducted to investigate the impact of choline chloride on the liver tumour promoting activity of phenobarbital and DDT in diethylnitroamine-initiated Fischer 344 rats. Animals received approximately 500 mg/kg/day choline chloride. Following the end of the exposure period, the animals were kept on the same untreated diet as the control group until study termination at week 103. Histopathology was limited to the liver and organs that developed gross abnormalities. There were no significant differences between treated and control animals on survival rates, body weights, and relative liver weights. There were no increased number of neoplastic liver nodules, hepatocellular carcinomas, lung tumours, leukemia or other tumours between treated and control animals. The NOAEL for choline chloride in this study is 500 mg/kg-day (Shivapurkar *et al.*, 1986) [Kl. score = 3].

In humans, oral administration of 10,000 mg/day choline chloride in a pilot study treating a small number of patients with Alzheimer's disease resulted in a slight hypotensive effect (Boyd *et al.*, 1977). This dose was regarded as a LOAEL by the U.S. Institute of Medicine (IOM) Standing Committee on the Scientific Evaluation of Dietary Reference Intake (2000).

Inhalation

No adequate or reliable studies are available.

Dermal

No adequate or reliable studies are available.

G. Genotoxicity

In Vitro Studies

Choline chloride was not mutagenic to bacteria in reverse mutation assays (Haworth *et al.*, 1983, Litton Bionetics, 1977).

A small, but statistically significant, and dose-related increase in chromosomal aberrations was reported in Chinese Hamster Ovary (CHO) cells at doses of 50 and 500 µg/mL choline chloride in the absence of S9 only (Bloom *et al.*, 1982). No higher concentrations were examined. These results could not be confirmed in two studies using CHO cells at concentrations of choline chloride up to 5,000 µg/mL (Galloway *et al.*,1985).

In sister chromatid exchange (SCE) assays, ambiguous results were obtained in two parallel studies (at two different laboratories) in CHO cells at concentrations up to 50 and 5,000 µg/mL choline chloride, respectively. Cytotoxicity was observed at 5,000 µg/mL. In laboratory 2, the increase in SCEs, which was sporadic and not dose-related, that was observed with metabolic activation was not reproduced in laboratory 1. Laboratory 1 showed a weak positive at the top dose without metabolic activation, but a comparison with laboratory 2 was not possible due to the insufficient number of cells analysed (Bloom *et al.*, 1982; Galloway *et al.*, 1985).

Choline chloride was negative in a gene conversion assay with *Saccharomyces cerevisiae* strain D4 in the presence or absence of metabolic activation (Litton Bionetics, 1977; OECD, 2004).

In Vivo Studies

No studies are available.

H. Carcinogenicity

Oral

No studies are available.

Inhalation

No studies are available.

I. Reproductive Toxicity

No reliable studies have been conducted that address female fertility or reproductive toxicity by a relevant route of exposure.

J. Developmental Toxicity

Oral

Pregnant female mice were given in their feed 0, 1, 2.5, 5, or 10% choline chloride (0 or approximately 1,250, 4,160, 10,800, or 20,000 mg/kg choline chloride) on gestational days 1 to 18. Maternal body weight gain was reduced in all treated groups except for the 1,250

mg/kg group. Maternal weight gain of dams with embryonic/foetal absorptions showed no net weight gain at >4,160 mg/kg, but there was net weight loss in the 20,000 mg/kg group. All foetuses were resorbed in the 20,000 mg/kg group. Embryonic/foetal lethality of 35% and 69% were seen in the 4,160 and 10,800 mg/kg groups, respectively. No resorptions occurred in the 1,250 mg/kg group. Developmental toxicity was seen at >4,160 mg/kg group. There were no statistically significant increases in malformations in any dose group. The NOAEL for maternal and developmental toxicity is 1,250 mg/kg/day (BASF AG, 1966; OECD, 2004) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for choline chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The Standing Committee on the Scientific Evaluation of Dietary Reference Intakes selected hypotension as the critical effect from the study by Boyd *et al.* (1977) when deriving a Tolerable Upper Intake Level. Boyd *et al.* (1977) reported a LOAEL of 10,000 mg/day choline chloride (7,500 mg/day choline). An uncertainty factor of 2 was chosen because of the limited data regarding hypotension and the inter-individual variation in response to cholinergic effects. Thus, the value for the Tolerable Upper Intake Level or repeated exposure of adults to choline is 3,500 mg/day choline.

Note that the Australian National Health and Medical Research Council (2014) concluded that there are no data to suggest that there is increased susceptibility to choline during pregnancy or lactation; thus, the upper level of intake choline is the same for women during pregnancy or lactation as it is for adults (3,500 mg/day choline).

Oral Reference Dose (oral RfD)

An oral RfD for choline is derived as follows: the LOAEL of 7,500 mg/day from the Boyd *et al.* (1977) study is divided by an uncertainty factor of 2 to obtain a value of 3,500 mg choline/day or 50 mg choline/kg/day for a 70 kg person.

Oral RfD = 50 mg/kg/day [choline]

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (50 x 70 x 0.1)/2 = 175 mg/L [choline]

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2021).

B. Cancer

There are no carcinogenicity studies on choline chloride. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Choline chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Choline chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on choline chloride.

Table 2: Acute Aquatic Toxicity Studies on Choline Chloride

Test Species	Endpoint	Results (mg/L)[1]	Klimisch score	Reference
Oryzias latipes	96-hour LC_{50}	>100 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)
Leuciscus idus	96-hour LC_{50}	>10,000*	2	OECD (2004); ECHA
Daphnia magna	48-hour EC_{50}	349 (nominal and measured)	2	MOE Japan (1999b); OECD (2004)
Daphnia magna	48-hour EC_{50}	>500*	2	OECD (2004)
Pseudokirchneriella subcapitata	72-hour EC_{50}	>1,000 (nominal and measured)	1	MOE Japan (1999a); OECD (2004)

*78% aqueous solution of choline chloride

Chronic Studies

In a 21-day *Daphnia magna* reproduction test, the nominal and measured NOEC was reported to be 30.2 mg/L (MOE Japan, 1999d) [Kl. score = 1].

The NOEC from a 72-hr algae *Pseudokirchneriella subcapitata* study is 30.2 mg/L (MOE Japan, 1999c; OECD, 2004) [Kl. score = 1].

C. Terrestrial Toxicity

No data is available.

Choline is present in all plant and animal cells, mostly in the form of phospholipids (phosphotidylcholine or lecithin, lysophosphatidylcholine, choline plasmalogens and sphingomyelin), which are essential components of membranes (IOM, 2000).

D. Calculation of PNEC

The PNEC calculations for choline chloride follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (>100 mg/L), invertebrates (349 mg/L) and algae (>1,000 mg/L). Results from chronic studies are available for invertebrates (21-day NOEC = 30.2 mg/L) and algae (72-hour NOEC = 32 mg/L). On the basis that the data consists of chronic studies on two trophic level (albeit not on the species with the lowest $E(L)C_{50}$), an assessment factor of 100 has been applied to the lowest reported NOEC of 30 mg/L for *Daphnia*. The $PNEC_{aquatic}$ is 0.3 mg/L (0.22 mg/L for choline).

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.15 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1{,}000 \times PNEC_{water}$
$= (0.844/1280) \times 1{,}000 \times 0.22$
$= 0.15$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1{,}000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.092/1{,}000 \times 2400]$
$= 0.844\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 2.3 x 0.04

= 0.092 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ for choline is 0.007 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1{,}000 \times PNEC_{water}$

= (0.05/1500) x 1,000 x 0.22

= 0.007 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 2.3 x 0.02

= 0.05 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for choline is estimated to be 2.3 L/kg (OECD, 2004).

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Choline chloride is readily biodegradable and thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of -3.77, choline chloride does not meet the criteria for bioaccumulation.

The NOEC values from chronic toxicity studies on choline chloride are >0.1 mg/L. Thus, choline chloride does not meet the criteria for toxicity.

The overall conclusion is that choline chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, nitrogen oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Choline chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Australian National Health and Medical Research Council (2014). Nutrient Reference Values for Australia and New Zealand: Choline. Accessed at: https://www.nrv.gov.au/nutrients/choline

BASF AG (1963a). Toxicity of choline chloride 70 % in water; skin irritation after exposure to choline chloride. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1963b). Toxicity of choline chloride 70% in water; eye irritation. Department of Toxicology. Unpublished results. Study No. XIII 9. 01 Mar. 1963.

BASF AG (1966). Study on teratogenic effects of choline chloride in the mouse after oral application. Department of Toxicology. Unpublished results. Study No. XIV/156. 14 Oct. 1966.

BASF AG (1984). Department of Product Safety. Laboratory of Ecology. Pruefbericht ueber eine Untersuchung auf biologische Abbaubarkeit im BSB5-Test - Cholinchlorid (German). Test No. 01606. 16 Feb. 1984.BASF AG (2004b). Department of Product Safety. Unpublished calculation. Mackay Level I V2.11. 29 Jun. 2004.

Bloom A., Galloway, S., Nakamura, F.T., Teteviri, A., Armstrong, M., Lavappa, K.L., Duk, S., and Ahmed, M.A. (1982). Comparison of results for SCE and chromosome aberrations for eleven compounds tested in two laboratories by standardized methods. Environ. Mutagen. 4: 397.

Boyd, W.D., Graham-White, J., Blackwood, G., Glen, I., and McQueen, J. (1977). Clinical effects of choline in Alzheimer senile dementia. Lancet 2: 711.

Colgate-Palmolive (2003). Study No. DCR-200-137-TKL. TKL Research Inc. Paramus, NJ, USA. In: SCCNFP. Scientific Committee on Cosmetic Products and Non-Food Products. Choline Chloride. SCCNFP/0672/03. 9 Dec. 2003.

Department of the Environment, Water, Heritage and the Arts [DEWHA] (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA] (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Galloway, S.M., Bloom, A..D, Resnick, M., Margolin, B.H., Nakamura, F., Archer, P., and Zeiger, E, (1985). Development of a standard protocol for in vitro cytogenetic testing with Chinese hamster ovary cells: Comparison of results for 22 compounds in two laboratories. Environ. Mutagen. 7: 1-51.

Haworth, S., Lawlor, T., Mortelmans, K., Speck, W., and Zeiger, E. (1983). Salmonella mutagenicity test results for 250 chemicals. Environ. Mutagenesis Suppl. 1: 3-142.

Institute of Medicine [IOM] (2000). Dietary Reference Intakes for Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Pantothenic Acid, Biotin, and Choline. . Standing Committee on the Scientific Evaluation of Dietary Reference Intake, Institute of Medicine, National Academy Press, Washington D.C.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Litton Bionetics (1977). Mutagenic evaluation of compound FDA75-69.000067-48-1. choline chloride. FCC. Report No. PB-266 891. Mar. 1977.

MITI (1992). Biodegradation and Bioaccumulation Data of Existing Chemicals Based on the CSCL Japan. Edited by Chemicals Inspection & Testing Institute Japan, published by Japan Chemical Industry Ecology-Toxicology & Information Center. October 1992.

MOE Japan (1999a). Ministry of Environment. Acute toxicity study of choline chloride on the Orange killifish *Oryzias latipes*. Unpublished study. No. 1998-16.

MOE Japan (1999b). Ministry of Environment. Acute toxicity study of choline chloride on *Daphnia magna*. Unpublished study. No. 1998-14.

MOE Japan (1999c). Ministry of Environment. Acute toxicity study of choline chloride on the freshwater alga *Pseudokirchnerialla subcapitata*. Unpublished study. No. 1998-13.

MOE Japan (1999d). Ministry of Environment. Chronic toxicity study of choline chloride on the freshwater invertebrate *Daphnia magna*. Unpublished study. No. 1998-15.

OECD (2004). SIDS Initial Assessment Report for Choline chloride (CAS No. 67-48-1), UNEP Publications. Available at: http://www.inchem.org/documents/sids/sids/67481.pdf

Shivapurkar, N., Hoover, K.L., and Poirier, L.A. (1986). Effect of methionine and choline on liver tumor promotion by phenobarbital and DDT in diethylnitrosamine-initiated rats. Carcinogenesis 7: 547- 550.

Tunkel J., Howard, P.H., Boethling, R.S., Sitteler, W., and Loonen, H. (2000). Predicting ready biodegradability in the Japanese Ministry of international trade and industry test. Environ. Toxicol. Chem. 19: 2478-2485.

U.S. Environmental Protection Agency [EPA] (2016). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Zeisel, S.H., Story, D.C., Wurtman, R.J., and Brunengraber, H. (1980). Uptake of free choline by isolated perfused rat liver. Proc. Natl. Acad. Sci. USA 77(8): 4417-4419.

Zeisel, S.H., and Blusztajn, J.K. (1994). Choline and human nutrition. Ann. Rev. Nutr. 14: 269-296.

ACRYLAMIDE/SODIUM ACRYLATE COPOLYMER (CAS NO. 25085-02-3)
ACRYLAMIDE/AMMONIUM ACRYLATE COPOLYMER (CAS NO. 26100-47-0)
ACRYLAMIDE, SODIUM ACRYLATE POLYMER (CAS NO. 25987-30-8)
2-PROPENOIC ACID, POTASSIUM SALT, POLYMER WITH 2-PROPENAMIDE (CAS NO. 31212-13-2)
ACRYLATE TERPOLYMER (CAS NO. 903573-39-7)[1]
SILICONE BASED EMULSION NEUTRALISED POLYACRYLIC BASED STABILISER (NO CAS NO.)

This group contains a sodium salt of a polymer consisting of acrylic acid, methacrylic acid or one of their simple esters and three similar polymers. They are expected to have similar environmental concerns and have consequently been assessed as a group. Information provided in this dossier is based on acrylamide/sodium acrylate copolymer (CAS No. 25085-02-3).

This dossier on acrylamide/sodium acrylate copolymer and similar polymers presents the most critical studies pertinent to the risk assessment of these polymers in their use in coal seam gas activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-Propenoic acid, sodium salt, polymer with 2-propenamide

CAS RN: 25085-02-3

Molecular formula: $(C_3H_5NO.C_3H_4O_2.NA)_x$-

Molecular weight: No information is available. Based on the type and intended use of the copolymer, the molecular weight would likely range from 100,000 to > 3,000,000 daltons (Hamilton et al., 1997).

Synonyms: Acrylamide/sodium acrylate copolymer; 2-propenamide, polymer with 2-propenoic acid, sodium salt; 2-propenoic acid, sodium salt, polymer with 2-propenamide; 2-Propenamide-sodium 2 propenoate copolymer; sodium acrylate acrylamide polymer; sodium acrylate-acrylamide copolymer

SMILES: Not applicable.

II. PHYSICAL AND CHEMICAL PROPERTIES

No information is available.

III. ENVIRONMENTAL FATE PROPERTIES

No studies are available. The acrylamide/sodium acrylate copolymer is not expected to be readily biodegradable. The physico-chemical properties of the copolymer would preclude it from undergoing significant biodegradation (Guiney et al., 1997). Biodegradation is limited due to the very high molecular weight and the low water solubility of the copolymer. The copolymer will likely bind tightly to organic matter found within soils and sediments (Guiney et al., 1997). The copolymer is not expected to bioaccumulate because of its poor water solubility and high molecular weight.

[1] CAS name: 2-Propenoic acid, polymer with sodium 2-hydroxy-3-(2-propen-1-yloxy)-1-propanesulfonate (1:1) and alpha-sulfo-omega-(2-propen-1-yloxy)poly(oxy-1,2-ethanediyl) ammonium salt (1:1), sodium salt

IV. HUMAN HEALTH HAZARD ASSESSMENT

No studies are available.

NICNAS has assessed acrylamide/sodium acrylate copolymer in an IMAP Tier 1 assessment and considers it a "polymer identified as a low concern to human health by application of expert validated rules[2]."

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No toxicological reference values or drinking water guidance values were developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Acrylamide/sodium acrylate copolymer does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

No studies are available. Acrylamide/sodium acrylate copolymer is expected to be a low concern for toxicity to aquatic organisms (Guiney et al., 1997). Due to its poor solubility and high molecular weight, it is not expected to be bioavailable. It does not contain any reactive functional groups (i.e., cationic groups).

A. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Acrylamide/sodium acrylate copolymer is not readily biodegradable; thus, it meets the screening criteria for persistence.

Acrylamide/sodium acrylate copolymer is expected to have a very high molecular weight and poor water solubility. It is not expected to be bioavailable. Thus, this copolymer does not meet the criteria for bioaccumulation.

There are no aquatic toxicity studies on acrylamide/sodium acrylate copolymer. It is expected to have low concern for aquatic toxicity because of its very high molecular weight and poor water solubility. Thus, the copolymer does not meet the criteria for toxicity.

The overall conclusion is that acrylamide/sodium acrylate copolymer is not a PBT substance.

[2] https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-i-human-health-assessments#cas-A_25085-02-3

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Burning produces harmful and toxic fumes. Heat from fire may melt, decompose polymer and generate flammable vapours. Combustion products may include: Nitrogen oxides, carbon monoxide, carbon dioxide and unburned hydrocarbons (smoke). Dust can accumulate static charges which can cause an incendiary electrical discharge. Fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source, is a potential dust explosion hazard.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Potential combustible dust hazard. Avoid generating dust. Creates dangerous slipping hazard on any hard smooth surface.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid dust accumulation in enclosed space. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Electrostatic charge may build up during handling. Equipment, container and metal containers should be grounded and bonded.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Use adequate ventilation to avoid excessive dust accumulation. Store away from excessive heat and away from strong oxidising agents. Take measures to prevent the build-up of electrostatic charge.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure limit for acrylamide/sodium acrylate copolymer.

Engineering Controls

Use in a well-ventilated area. Avoid creating dust. Take precautionary measures against static charge.

Personal Protection Equipment

Respiratory Protection: Not normally needed; however, if significant exposures are possible, then the following respirator is recommended: Dust/mist respirator.

Hand Protection: Normal work gloves.

Skin Protection: Normal work coveralls.

Eye Protection: Wear safety glasses or goggles to protect against exposure.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Acrylamide/sodium acrylate copolymer is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII.REFERENCES

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Guiney, P. D., McLaughlin, J. E., Hamilton, J. D., and Reinert, K. H. (1997). Dispersion Polymers. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs (Hamilton, J.D. and Sutcliffe, R. eds.), pp. 147-165, Van Nostrand Reinhold.

Hamilton, J. D., Vasconcellos, S. R., and Keener, R. L. (1997). Introduction. In: Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs (Hamilton, J.D. and Sutcliffe, R. eds.), pp. 3-15, Van Nostrand Reinhold.

Klimisch, H. J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol Pharmacol. 25:1-5.

COPPER (II) SULFATE

This dossier on copper (II) sulfate (CAS RN 7758-98-7) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): copper (II) sulfate

CAS RN: 7758-98-7

Molecular formula: $CuSO_4$

Molecular weight: 159.61 g/mol

Synonyms: copper sulfate;cupric sulfate; copper sulphate

Smiles: [O-]S(=O)(=O)[O-].[Cu+2]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Copper (II) Sulfate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White-green, odourless, amorphous powder or crystalline solid	2	ECHA
Melting Point	110°C @ 101.3 kPa	2	ECHA
Boiling Point	560°C @ 101.3 kPa	2	ECHA
Density	3600 kg/m^3 (temperature not available)	2	ECHA
Vapour Pressure	Not applicable as substance is solid	-	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	ECHA
Water Solubility	22 g/L at 25°C	2	ECHA
Flash Point	Not applicable as substance is solid	-	ECHA
Auto flammability	Not applicable as substance is solid	-	ECHA
Viscosity	Not applicable as substance is solid	-	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Copper is a natural element and transition metal with more than one oxidation state. Copper in its metallic form (Cu°) is not available. Copper needs to be transformed to its ionic forms to become available for uptake by living organisms (ECHA).

B. Biodegradation

Biodegradation as used for organic substances does not apply to inorganic substances such as copper and its compounds..

C. Environmental Distribution

In soil, copper (II) sulfate has a reported soil partition coefficient (Kd) value of 2,120 L/kg (ECHA). Based on this value, if released to soil, the substance is expected to strongly adsorb. Soil pH is a key factor governing attenuation (ECHA).

If released to water, copper binds to the sediment organic carbon (particulate and dissolved) and to the anareobic sulphides, resulting in the formation of copper sulfide (CuS). CuS has a very low stability constants/solubility limit (LogK=-41, ECHA) and therefore the 'insoluble' CuS keeps copper in the anaerobic sediment layers, limiting the potential for remobilization of Cu-ions into the water column (ECHA).

D. Bioaccumulation

Because copper is an essential nutrient, all living organisms have well developed mechanisms for regulating copper intake, copper elimination and internal copper binding. There is a considerable amount of copper accumulation data available, that could potentially be used to calculate bioconcentration factors (BCF) and bioaccumulation factors (BAF) and assess the corresponding potential risks in aquatic food chains. The information in the accumulation section demonstrates that copper is well regulated in all living organisms and that highest BCF/BAF values are noted when copper concentrations in water, sediments and soils are low and for organisms/ life stages with high nutritional needs. The BCF/BAF values therefore have no ecotoxicological meaning. Importantly, the literature review demonstrates that copper is not biomagnified in aquatic or terrestrial ecosystems (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Copper is an essential metal present in human body tissues and fluids at concentrations of parts per million or parts per billion. It is also under tight homeostatic mechanisms that can control excess copper exposure by changing the rate of systemic uptake or excretion via the bile in humans. Therefore, in assessing the human health effects of copper the essentiality and homeostaic mechanisms have to be taken into account (ECHA).

Copper (II) sulfate has low acute toxicity by the oral and dermal routes. This substance was determined to be severely irritating to the eyes. It is not irritating to the skin and is not a skin sensitiser. No systemic effects were observed in sub-chronic oral or inhalation toxicity studies. It is not genotoxic, nor is it a reproductive or developmental toxicant.

B. Acute Toxicity

Oral

In an OECD 401 (Acute Oral Toxicity) study, an LD_{50} of 481-482 was established for copper (II) sulfate (ECHA). [KI score = 1].

Inhalation

No data available (ECHA).

Dermal

In an OECD Guideline 402 study a LD_{50} is >2000 was established for copper (II) sulfate (ECHA) [Kl Score = 1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of copper (II) sulfate using New Zealand White rabbits. Copper (II) sulfate was found to be non-irritating to the skin of rabbits (ECHA) [KI score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using copper (II) sulfate. This substance is considered severely irritating to the eyes of rabbits (ECHA) [Kl score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study (i.e., Buehler test) was performed on Pirbright-Hartley guinea pigs. Copper (II) sulfate did not induce skin sensitisation in this study (ECHA) [Kl score = 1].

E. Repeated Dose Toxicity

Oral

An EU Method B.26 (Sub-Chronic Oral Toxicity Test: Repeated Dose 90-Day Oral Toxicity Study in Rodents) was performed using male and female F344/N rats. Copper (II) sulfate was administered orally via feed for 92 days at a dose of 0, 500, 1000, 2000, 4000 or 8000 ppm (providing estimated intakes of 0, 8, 17, 34, 67 or 138 mg Cu/kg bw/day). A NOAEL of 1,000 ppm (equivalent to 16.7 mg Cu/kg bw/day was established based on the absence of hyperplasia and hyperkeratosis of the forestomach and absence of inflammation of the liver (ECHA) [KI score = 1].

Inhalation

An OECD Guideline 412 study (Subacute Inhalation Toxicity: 28-Day study) was performed using male and female Sprague-Dawley rats. Copper (II) sulfate was administered via whole

body inhalation for 28 days. Inhalation exposure with cuprous oxide markedly affected neutrophil numbers at all exposure levels in this study (0.2, 004, 0.8, and 2.0 mq/m^3). However, the effects were reversible and there were no observed test substance-related effects on hematology parameters, bronchoalveolar lavage fluid (BALF) parameters, or lung histopathology following the 13-week recovery period. The NOAEL for the neutrophil effects is therefore considered> 2.0 mg/m^3. (ECHA) [KI score = 1].

Dermal

No data were available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on copper (II) sulfate are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Copper (II) Sulfate

Test System[1]	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) Salmonella typhimurium strains TA98, TA100, TA1535, TA1537, TA102	-	-	1	ECHA

*+, positive; -, negative.

In Vivo Studies

An EU Method B. 12 (Mutagenicity-In Vivo Mammalian Erythrocyte Micronucleus Test) study was performed using CD-1 mice exposed to copper (II) sulfate via oral gavage. Copper (II) sulfate did not induce micronuclei in the polychromatic erythrocytes of the bone marrow of CD-1 mice, which indicates that this substance is not genotoxic (ECHA) [KI score = 1].

An OECD Guideline 486 (Unscheduled DNA Synthesis [UDS] Test with Mammalian Liver Cells *in vivo*) was performed using Wister rats exposed to copper (II) sulfate via oral gavage. The results indicate that copper (II) sulfate is not genotoxic because it did not induce cell repair greater than 1.0% (ECHA) [KI score = 1].

G. Carcinogenicity

Available studies on the carcinogenicity of copper are of limited value to ascertain the carcinogenic potential copper compounds. This is due to the fact that these studies are limited due to shorter exposure periods (<2 years) small sample sizes and limited histopathologic examination. However, when the 3 available studies are assessed on an overall balanced approach, they give useful information as to the carcinogenic potential of copper compounds (ECHA).

These results indicate that copper sulphate and other copper salts do not appear to have carcinogenic potential even at very high dose levels of up to 120 mg Cu/kg/bw/day (ECHA) [Kl. Score =3]. In addition, one of the studies indicates that excess copper may have a

protective effect on known carcinogens. In summary, the findings of these studies do not raise concerns with respect to carcinogenic activity (ECHA).

H. Reproductive Toxicity

An OECD Guideline 416 study (Two-Generation Reproduction Toxicity Study) was performed on male and female Crl:CD rats. Copper (II) sulfate was administered orally at doses of 0, 100, 500, 1000 and 1500 ppm via their feed for 70 days. There were no effects up to 1,500 ppm so the NOAEL was determined to be 1,500 ppm or 23.6 mg/kg/bw/day for reproductive toxicity The NOAEL for P1 and F1 rats and F1 and F2 offspring during lactation was 1000 ppm, based on reduced spleen weight in P1 adult females, and F1 and F2 male and female weanlings at 1500 ppm however the transient reduced spleen weights are not considered a reproductive endpoint as it did not affect growth or fertility. (ECHA). [KI score = 1].

I. Developmental Toxicity

New Zealand White rabbits were exposed to copper (II) sulfate via oral gavage (0, 7.5, 15 or 30 mg Cu/kg bw/day as copper hydroxide) during Day 7 to Day 28 of gestation. Maternal toxic effects were observed at all dose levels, and they were considered treatment related. Therefore, the maternal NOAEL was determined to be 7.5 mg/kg/bw/day based on based on mortality, gastric ulcers, haemolytic anaemia, renal damage, increased malformation, reduced foetal weights and increased resorptions. There was evidence of compound-related developmental toxicity at 30 mg Cu/kg bw/day. Mean foetal weights were reduced by 12 % relative to the control group. Foetal resorptions appeared slightly increased at this level and 4 foetuses (2 each from 2 litters) were observed with omphalocele (protrusion of intestines at the umbilicus). No evidence of developmental toxicity was observed at the other dose levels. One foetus of the 7.5 mg Cu/kg bw/day group had anasarca, domed head and a short tail. This finding was considered to be incidental since only one foetus showed these changes and no dose-response was observed. Therefore, a NOAEL of 15 mg/kg/bw/day was established for developmental toxicity (ECHA). [Kl. Score = 2].

An OECD Guideline 414 study (Prenatal Developmental Toxicity Study) was performed on Crl:CD rats. These animals were exposed to copper (II) sulfate via their feed. There were no reproductive effects observed at any concentration, so the NOAEL was determined to be 1,000 ppm for developmental effects [KI score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for copper (II) sulfate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

An oral toxicological reference value was not derived for copper (II) sulfate.

The Australian drinking water guideline values for copper is 2 mg/L (ADWG, 2021).

B. Cancer

Copper (II) sulfate is not considered a carcinogen. Thus, a cancer reference value will not be calculated for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Copper (II) sulfate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Copper is an essential micronutrient, needed for optimal growth and development of micro-organisms, plants and animals. Copper and copper compounds may present a hazard for the environment depending on the release/bioaccessibility of copper ions and on the conditions of the receiving environment (pH, hardness, presence and type of organic matter, anions and competing cations). Copper (II) sulfate in acute aquatic toxicity studies is very toxic and in chronic aquatic toxicity studies is very toxic with long lasting effects.

B. Aquatic Toxicity

Acute Studies

USEPA (1985) reported acute toxicity data for copper in freshwater species in 41 genera. At a hardness of 50 mg/L, the values ranged from 17 µg/L for *Ptychocheilus* to 10,000 µg/L for *Acroneuria*. Skidmore & Firth (1983) found the acute toxicity of copper for ten Australian species ranged from 200 µg/L to 7800 µg/L. Bacher & O'Brien (1990) reported a range for Australian species ranged from 40 µg/L to 21,000 µg/L (ANZG, 2021).

Chronic Studies

The ANZG water quality guideline (2021) derived a very high reliability default guideline value (DGVs) for copper in freshwater from 130 data points covering 4 taxonomic groups, and these were adjusted to a common hardness of 30 mg/L as $CaCO_3$, as follows (data are reported as geometric means of NOEC after adjustment from other chronic end-points (pH range was 6.96 to 8.61):

- Fish: 10 species, 2.6 µg/L (*Ptylocheilus oregonensis*, from 7-day LC_{50}) to 131 µg/L (*Pimephales promelas*, 7-day LC_{50}); seven species had geometric means <25 µg/L
- Crustaceans: five species, 1.7 µg/L (*D. pulex* and *G. pulex*, NOEC, reproduction & mortality) to 12.1 µg/L (*Hyalella azteca*, from 10 to 14-day LC_{50})
- Insects: three species, 2.2 µg/L (*Tanytarsus dissimilis*, from 10-day LC*50*) to 11 µg/L (*Chironomus tentans*, 10 to 20-day LC_{50})
- Molluscs: three species, 1.64 µg/L (*Flumicola virens*, from 14-day LC_{50}) to 56.2 µg/L (*Corbicula manilensis*, from 7 to 42-day LC_{50}). The latter figure was not included in calculations as it was outside the pH range.

Additional chronic aquatic toxicity data is found in the ANZG Technical Brief (ANZG, 2021).

C. Sediment Toxicity

The freshwater sediment effect records include 62 high quality single-species chronic NOEC/L(E)C_{10} values from 6 different sediment- dwelling species of relevance. The individual NOEC values range between 18.3 mg/kg dry weight and >3,158 mg/kg (min-max value). Large intra-species variability are observed due to variations in organic carbon (OC) content and acid volatile sulphide (AVS) content of the sediments. Normalization of the effects data for AVS was not possible and therefore only NOEC/(L(E)C_{10} values generated under conditions that represent "aerobic" conditions (Low AVS) were retained (ECHA).

D. Terrestrial Toxicity

The copper terrestrial effects database contains more than 250 high quality, chronic NOEC/EC_{10} values. The chronic NOECs/EC_{10}s vary between 8.4 mg/kg for *Eisenia andrei* (cocoon production) and 2,402 mg/kg (maize respiration). The lowest value is actually below the limit for essentiality for the species (OECD, 2018). As described in ECHA, considering the importance of bioavailabilty for reducing the intra-species variability, the database includes supportive information related to the development/validation of the terrestrial copper bioavailability regression models. The bioavailability regression models are used for normalizing the NOECS (ECHA).

E. Calculation of PNEC

The PNEC calculations for copper (II) sulfate follow the methodology discussed in DEWHA (2009).

PNEC water

The ANZG water quality guideline (2021) derived a very high reliability DGV for copper in freshwater. The DGVs for 99, 95, 90 and 80% species protection are 1 µg/L, 1.4 µg/L, 1.8 µg/L and 2.5 µg/L, respectively. The 95% species protection level for copper in freshwater (1.4 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems. It applies to waters of hardness of 30 mg/L as $CaCO_3$ (ANZG, 2021).

PNEC sediment

In the ECHA REACH database (ECHA), a $PNEC_{sediment}$ was derived for copper (II) sulfate using a weight of evidence approach and an assessment factor of 1. The $PNEC_{sediment}$ was determined to be 87 mg/kg sediment dry weight.

PNEC soil

In the ECHA REACH database (ECHA), a $PNEC_{soil}$ was derived for copper (II) sulfate using a bioavailability regression model and an assessment factor of 1. The $PNEC_{soil}$ was determined to be 65 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008). Note that PBT assessments are not relevant for metals (ECHA). Despite this, efforts were made to consider PBT for copper sulfate.

Copper (II) sulfate is an inorganic substance. Biodegradation is not applicable. For the purposes of this PBT assessment, the persistent criteria are not considered applicable..

Because copper is an essential nutrient, all living organisms have well developed mechanisms for regulating copper intake, copper elimination and internal copper binding. Bioaccumulation is not relevant. Further, copper is not biomagnified in aquatic or terrestrial ecosystems. As a result, bioaccumulation criteria are not considered applicable.

The chronic toxicity data on copper has a NOEC < 0.1 mg/L. Acute E(L)C50 values are < 1 mg/L. Thus, copper (II) sulfate does meet the criteria for toxicity.

The overall conclusion is that copper (II) sulfate overall is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Oral-Acute Tox.: 4H302: Harmful if swallowed.

Irritation-Eye category 2:H319: Causes serious eye irritation.

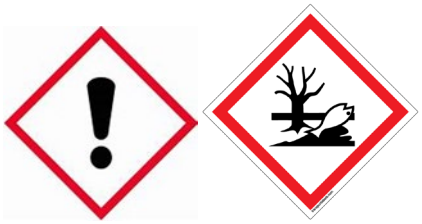
Irritation-Skin category 2: H315: Causes skin irritation.

Environmental: Aquatic: H410: Very toxic to aquatic life with long lasting effects.

B. Signal word

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Please refer to the product SDS for additional information and confirmation of the information provided herein.

<u>Eye Contact</u>

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for copper (II) sulfate.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking, and using the lavatory; and at the end of the working

period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: 3288 (Solid)

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZG (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Bacher GJ & O'Brien TA. (1990). The sensitivity of Australian freshwater aquatic organisms to heavy metals. SRS 88/018. Victorian Environment Protection Authority, Melbourne.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2018). SIDS Initial Assessment Report: Copper and Copper Compounds. https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=e7b50eea-4f93-4918-9645-622c16b256ff

Skidmore JF & Firth IC. (1983). Acute sensitivity of selected Australian freshwater animals to copper and zinc. Australian Water Resources Council, technical paper 81, Australian Government Publishing Service, Canberra.

United States Environmental Protection Agency [USEPA]. (1985). Ambient water quality criteria for copper —1984. United States Environmental Protection Agency, Washington DC. EPA-440/5-84-031.

CRYSTALLINE SILICA, QUARTZ (CAS NO. 14808-60-7)
CRYSTALLINE SILICA, CRISTOBALITE (CAS NO. 14464-46-1)
CRYSTALLINE SILICA, TRIDYMITE (CAS NO. 15468-32-3)
NON-CRYSTALLINE SILICA (IMPURITY) (CAS NO. 7631-86-9)
DIATOMACEOUS EARTH (CAS NO. 61790-53-2)
DIATOMACEOUS EARTH, CALCINED (CAS NO. 91053-39-3)

This dossier on crystalline silica, quartz, cristobalite and tridymite; non-crystalline silica (impurity); diatomaceous earth; and diatomaceous earth, calcined presents the most critical studies pertinent to the risk assessment of these substances in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

For the purpose of this dossier, crystalline silica, quartz (CAS No. 14808-60-7) has been reviewed as representative of crystalline silica cristobalite and tridymite, and non-crystalline silica (impurity). Crystalline silica, quartz is also considered representative of diatomaceous earth and diatomaceous earth, calcined, as they both consist mainly of silicon dioxide.

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dioxosilane

CAS RN: 14808-60-7

Molecular formula: SiO_2

Molecular weight: 60.084 g/mol

Synonyms: Cristobalite, Dioxide, Silicon

SMILES: O=[Si]=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Silica is an off-white granule that occurs naturally in various crystalline and amorphous or other non-crystalline forms. Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. Other crystalline forms of silica include cristobalite, tripoli and tridymite. Particle size is a key determinate of silica toxicity, since toxicity is restricted to particles that are small enough to be deposited into the target regions of the respiratory tract (OECD, 2011).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Crystalline silica is characterised by silicon dioxide (SiO_2) molecules oriented in fixed, periodic patterns to form stable crystals. The primary crystalline form of silica is quartz. It is a stable solid under typical environmental conditions. It will not biodegrade, bioaccumulate, nor will it sorb to sediments or soils.

B. Biodegradation

No data are available. Based on the crystalline form of the substance, it is not expected to biodegrade.

C. Environmental Distribution

No experimental data are available for crystalline silica. As a stable inorganic solid, it is not soluble in water, and it will not sorb to soils or sediment.

D. Bioaccumulation

There are no bioaccumulation studies on crystalline silica.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Human exposure to crystalline silica via inhalation can lead to silicosis, lung cancer and pulmonary tuberculosis (WHO, 2000).

B. Acute Toxicity

No adequate acute oral, dermal or inhalation exposure studies are available for quartz, cristobalite or tridymite.

Most acute toxicity studies for quartz or cristobalite were conducted using intratracheal instillation. Intratracheal instillation is the introduction of the substance directly to the trachea and is used to test respiratory toxicity of a substance.

Single intratracheal instillation of quartz caused inflammatory effects and formation of discrete silicotic nodules in rats, mice and hamsters (IARC, 2012; WHO, 2000). Other effects like oxidative stress, cellular proliferation and increases in water, protein and phospholipid content of rat lungs, apoptosis (programmed cell death) and lung cancer were also noted.

In an acute dose study, rats were dosed once with 0, 0.75, 1.5, 3.0, 6.0 or 12 mg/kg bw/day quartz by intratracheal instillation (Seiler et al., 2001). The lowest observed adverse effect level (LOAEL) of 0.75 mg/kg bw/day was derived from these studies.

Two other similar studies of single intratracheal instillation of quartz reported higher LOAELs in rats (3 and 40 mg/kg bw/day) based on inflammation and fibrosis (Saffiotti et al., 1996).

C. Irritation

No data available.

D. Sensitisation

No data available.

E. Repeated Dose Toxicity

Oral

No data available.

Inhalation

Repeated inhalation exposure of crystalline is known to cause adverse effects (IARC, 2012). Silicosis has been identified as the main non-cancer effect of silica exposure, although available epidemiologic data as well as animal data provide evidence for several other effects associated with silica exposure, such as silicotuberculosis, enlargement of the heart (cor pulmonale), interference with the body's immune system and damage to the kidneys (Health Canada, 2013).

Dermal

No data available.

F. Genotoxicity

No data available.

G. Carcinogenicity

Oral

No data available.

Inhalation

The International Agency for Research on Cancer (IARC) has classified crystalline silica as a Group 1 carcinogen, as there was sufficient evidence for carcinogenicity in experimental animals and sufficient evidence for carcinogenicity of inhaled crystalline silica from occupational sources (IARC, 1997; IARC, 2012).

H. Reproductive Toxicity

No data available.

I. Developmental Toxicity

No data available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicity information on crystalline silica is inadequate and/or unreliable for deriving toxicological reference and drinking water guidance values for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Crystalline silica does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Although no data are available, crystalline silica is expected to exhibit low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

No aquatic toxicity data were available.

C. Terrestrial Toxicity

No terrestrial toxicity data were available.

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Crystalline silica is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to crystalline silica.

As an inorganic complex it is not expected to bioaccumulate. Thus, crystalline silica does not meet the screening criteria for bioaccumulation.

Crystalline silica is not expected to cause adverse effects in environmental receptors. Thus, this substance does not meet the screening criteria for toxicity.

Therefore, crystalline silica is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

H373 – may cause damage to organs through prolonged or repeated exposure.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention if symptoms persist.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Get medical attention if respiratory irritation develops or breathing becomes difficult.

Ingestion

Rinse mouth. Do not induce vomiting. Get medical attention if symptoms occur.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use extinguishing media appropriate for surrounding material.

Specific Exposure Hazards

Reacts with hydrofluoric acid (HF) forming toxic gas (SiF_4).

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Pick up mechanically – vacuum up. Avoid generating dust. If formation of dust cannot be avoided, use respiratory filter device. Dispose of the material collected according to regulations.

D. Storage And Handling

General Handling

Handle in accordance with good industrial hygiene and safety practice. Avoid contact with eyes, skin and clothing. Avoid dust formation. Do not breathe dust. Wash thoroughly after handling. Use with adequate ventilation.

Storage

Provide adequate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits. Keep containers tightly closed in a dry, cool, well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has established an occupational exposure standard for exposure to crystalline silica of an 8-hour time weighed average (TWA) exposure limit of 0.05 mg/m^3.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls

to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; as well as before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Crystalline silica is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Health Canada. (2013). Environment Canada, Health Canada. Screening Assessment for the Challenge: Quartz (CAS 14808-60-7) and Cristobalite (CAS 14464-46-1). June 2013. https://www.ec.gc.ca/ese-ees/1EB4F4EF-88EE-4679-9A6C-008F0CBC191C/FSAR_B12%20-%2014464-46-1%20%26%2014808-60-7%20%28QC%29_EN.pdf

IARC. (1997). Silica, some silicates, coal dust and Para-aramid fibrils. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 15-22 October 1996. IARC Monogr Eval Carcinog Risks Hum. 1997;68:1–475.

IARC. (2012). Silica dust, crystalline, in the form of quartz or cristobalite. International Agency for Research on Cancer (IARC) working group on the evaluation of carcinogenic risks to humans, Lyon, France, 17-24 March, 2009. IARC Monogr Eval Carcinog Risks Hum. 2012;100C:355–405

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2011). OECD -SIDS Initial Targeted Assessment Profile on Quartz and Cristobalite, SIAM 32, 19-21 April 2011. https://hpvchemicals.oecd.org/ui/handler.axd?id=b68bb357-e6dd-4db9-b05c-8148223fc0ff.

Saffiotti, U., Williams, O., Lambert, N., Daniel, N., Kaighn, M.E., Mao, Y., Shi, X. (1996). Carcinogenesis by crystalline silica: animal, cellular, and molecular studies. In:Castranova V, Vallyathan V, Wallace WE, eds. Silica and silica-induced lung diseases. Boca Raton, FL, CRC Press, pp. 345–381.

Seiler, F., Rehn, B. and Bruch, J. (2001). Evidence of a no-effect level in silica–induced rat lung mutagenicity but not in fibrogenicity. Archives of Toxicology 74: 716-719.

WHO. (2000). Concise International Chemical Assessment Document 24 - Crystalline Silica, Quartz. Produced within the framework of the Inter-Organization Programme for the Sound Management of Chemicals. WHO Geneva.

OCTAMETHYLCYCLOTETRASILOXANE (CAS RN 556-67-2)
DECAMETHYLCYCLOPENTASILOXANE (CAS RN 541-02-6)
DODECAMETHYLCYCLOHEXASILOXANE (CAS RN 540-97-6)

This dossier on three cyclic polyorganosiloxanes (octamethylcyclotetrasiloxane, decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane) does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of these cyclic polyorganosiloxanes in their use in coal seam gas extraction activities. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2,2,4,4,6,6,8,8-octamethyl-1,3,5,7,2,4,6,8-tetroxatetrasilocane

CAS RN: 556-67-2

Molecular formula: $C_8H_{24}O_4Si_4$

Molecular weight: 296.61 g/mol

Synonyms: Octamethylcyclotetrasiloxane; cyclic polyorganosiloxanes

SMILES: C[Si]1(O[Si](O[Si](O[Si](O1)(C)C)(C)C)(C)C)C

Chemical Name (IUPAC): 2,2,4,4,6,6,8,8,10,10-decamethyl-1,3,5,7,9,2,4,6,8,10-pentoxapentasilecane

CAS RN: 541-02-6

Molecular formula: $C_{10}H_{30}O_5Si_5$

Molecular weight: 370.77 g/mol

Synonyms: Decamethylcyclopentasiloxane

SMILES: C[Si]1(O[Si](O[Si](O[Si](O[Si](O1)(C)C)(C)C)(C)C)(C)C)C

Chemical Name (IUPAC): Dodecamethylcyclohexasiloxane

CAS RN: 540-97-6

Molecular formula: $C_{12}H_{36}O_6Si_6$

Synonyms: Cyclohexasiloxane, 2,2,4,4,6,6,8,8,10,10,12,12-dodecamethyl-; Cyclohexasiloxane, dodecamethyl-

Molecular weight: 444.92 g/mol

SMILES: C[Si]1(O[Si](O[Si](O[Si](O[Si](O[Si](O1)(C)C)(C)C)(C)C)(C)C)(C)C)C

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Cyclic Polyorganosiloxanes

Property	Octamethyl cyclotetrasiloxane CAS RN 556-67-2	Decamethyl cyclopentasiloxane CAS RN 541-02-6	Dodecamethyl cyclohexasiloxane CAS RN 540-97-6	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless, volatile liquid	liquid	liquid	2	ECHA
Melting Point	17.7°C @ 101.3 kPa	-38°C @101.3 kPa	-3°C @101.3 kPa	2	ECHA
Boiling Point	175°C @ 101.3 kPa	210°C @101.3 kPa	245°C @101.3 kPa	2	ECHA
Density	950 kg/m^3 @ 20°C	960 kg/m^3 @ 20°C	980 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	132 Pa @ 25 °C	33.2 Pa @ 25 °C	4.7 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	6.98 @ 21.7 °C	8.07 @ 24.6 °C	8.87	2,1,2	ECHA
Water Solubility	0.000056 g/L @ 23°C	0.000017 g/L @ 23°C	0.0000051 g/L @ 23°C	2	ECHA
Viscosity	1.6 mm^2/s @ 20°C (kinematic)	3.7 mm^2/s @ 25°C (kinematic)	5.6 mm^2/s @ 20°C (kinematic)	2	ECHA
Dissociation Constant (pKa)	There are no ionizable groups	There are no ionizable groups	There are no ionizable groups	-	ECHA
Henry's Law Constant	1.2 x 10^6 Pa m^3/mol @ 21.7 °C	3.3 x 10^6 Pa m^3/mol @ 24.6 °C	2.5 x 10^6 Pa m^3/mol @ 23.6 °C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Cyclic polyorganosiloxanes are volatile and insoluble in water (hydrophobic). They are not readily biodegradable in water or sediment but are susceptible to biodegradation in soil. They have a moderate to high potential for bioaccumulation. However, they are not expected to biomagnify in the food chain.

B. Partitioning

All three cyclic polyorganosiloxanes are essentially insoluble in water. Volatilization from water surfaces is expected to be an important fate process based upon their Henry's Law constant. Estimated volatilization half-lives for a model river and model lake are 5 hours and 6.8 days, respectively (for octamethyltetrasiloxane). However, volatilization from water surfaces is expected to be attenuated by adsorption to suspended solids and sediment in the water column (Pubchem).

C. Biodegradation

Overall, none of the cyclic polyorganosiloxanes are readily biodegradable under test conditions.

In an OECD 310 (Ready Biodegradability test), octamethylcyclotetrasiloxane (CAS RN 556-67-2), degraded 3.7% in 29 days indicating that it is not readily biodegradable in water (ECHA). [KI Score =

1]. However, abiotic hydrolysis in the water compartment is a key degradation process in the environment. In the case of this substance, the longest observed half-life was for pH 7.0, with an average half-life of 3.9 days at 25°C. For 20°C, the lowest temperature allowed in a standard OECD 301 ready biodegradability study, the calculated hydrolysis half-life for D4 at pH 7.0 is 5.8 ± 1.7 days, which clearly meets the 16 day threshold criterion for rapid degradability (ECHA).

Decamethylcyclopentasiloxane (CAS RN 541-02-6) was evaluated in an OECD 310 Ready Biodegradability test. The results from the biodegradability test showed a rate of 0.14% in 28 days which indicates that this substance is not readily biodegradable in water (ECHA). [KI Score = 1].

In an OECD 310 Ready Biodegradability test, dodecamethylcyclohexasiloxane (CAS RN 540-97-6), degraded 4.47% after 28 days (ECHA). [KI Score = 1]. These results indicate that this substance is not readily biodegradable in water.

Degradation in sediment has been shown to be slow. An OECD 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) was used to determine the half-life for octamethylcyclotetrasiloxane is 365 days at 24°C (ECHA). [KI Score = 1].

An OECD 308 (Aerobic and Anaerobic Transformation in Aquatic Sediment Systems) was used to determine that the half-life for decamethylcyclopentasiloxane is 1,200 days under aerobic conditions and 3,100 days under anaerobic conditions at 24°C (ECHA). [KI Score = 1].

There were no persistence studies conducted for dodecamethylcyclohexasiloxane. .

The fate of cyclic volatile methyl siloxanes in soil is strongly dependent both on the mineralogy of the soil and soil moisture levels. In a highly weathered soil with a high clay content, the degradation half-lives for these three substances were all less than 2 days at the same relative humidity (32%; in a closed system). The rate of degradation was slower in soils with a lower proportion of different clay minerals (NICNAS, 2020a).

D. Environmental Distribution

Based on an OECD 106 batch equilibrium method test, log K_{oc} values of 4.22 L/kg and 5.17 L/kg were derived for octamethylcyclotetrasiloxane (CAS RN 556-67-2) and decamethylcyclopentasiloxane (CAS RN 541-02-6) (ECHA). [Kl. Score = 1].

No experimental data are available for dodecamethylcyclohexasiloxane (CAS RN 540-97-6). A log K_{oc} value of 5.9 L/kg was experimentally derived (ECHA). [Kl. Score = 2].

Based upon these K_{oc} values, if released to soil, these cyclic polyorganosiloxanes have a high potential for adsorption and a low potential for mobility. If released to water, based on their K_{oc} and insolubility, these substances would also strongly adsorb to suspended solids and sediments.

E. Bioaccumulation

These three cyclic polyorganosiloxanes have moderate to high potential to bioaccumulate.

Octamethylcyclotetrasiloxane (CAS RN 556-67-2)has a very high potential to bioconcentrate in fish under optimised exposure conditions. The steady state BCF for the substance in fathead minnows (*Pimephales promelas*) was determined to be 12 400 L/kg after 28 days continuous exposure to radiolabelled test material in soft water at 21–22°C in an enclosed flow-through system. This study

did not identify any metabolites and the parent chemical was eliminated relatively slowly (NICNAS, 2020a).

A recent review of the available studies on the bioconcentration of decamethylcyclopentasiloxane (CAS RN 541-02-6) in fish recalculated BCF values for this chemical in the range 1040 to 4920 L/kg wet weight. The review of these studies highlighted the fact that depuration of the substance in fish is more rapid than would be expected for a very hydrophobic organic chemical. The faster than expected elimination of the substance in fish is attributed to biotransformation of the chemical into polar metabolites (NICNAS, 2020a).

The bioconcentration potential of dodecamethylcyclohexasiloxane (CAS RN 540-97-6) in aquatic life is moderate based on studies with fish and aquatic invertebrates. The steady state BCF for the chemical in the fathead minnow (*Pimephales promelas*) is in the range 240–1160 L/kg based on total radioactivity taken up during a 49 day exposure phase; depuration of the substance was reported to be slow. The majority of the tissue content (79%) was the parent chemical, although there was also an unidentified metabolite which accounted for 5% of the extracted radioactivity. The steady state BCF for the water flea, Daphnia magna, is approximately 2400 L/kg based solely on the uptake of the chemical (NICNAS, 2020a).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Cyclic polyorganosiloxanes exhibit low acute toxicity by the oral, dermal and inhalation routes. They are not a skin or eye irritant, nor are they considered to be skin sensitisers. Repeated oral, dermal or inhalation exposures did not identify significant or serious adverse health effects. The substances are not genotoxic, carcinogenic nor developmentally toxic. Octamethylcyclotetrasiloxane is considered to cause reproductive toxicity following inhalation exposure.

B. Acute Toxicity

Oral

In an OECD 401 (Acute Oral Toxicity) test for octamethylcyclotetrasiloxane (CAS RN 556-67-2), an oral LD_{50} of > 4,800 mg/kg bw was observed in male rats (ECHA). [KI Score = 2].

In an OECD 401 (Acute Oral Toxicity) test for decamethylcyclopentasiloxane (CAS RN 541-02-6), an oral LD_{50} of > 5,000 mg/kg bw was observed in male rats (ECHA). [KI Score = 1].

In an OECD 401 (Acute Oral Toxicity) test for dodecamethylcyclohexasiloxane (CAS RN 540-97-6), an oral LD_{50} of > 2,000 mg/kg bw was observed in male rats (ECHA) [KI Score = 1].

Inhalation

In an OECD 403 (Acute Inhalation Toxicity) test for octamethylcyclotetrasiloxane (CAS RN 556-67-2), the LC_{50} after 4 hours was determined to be 0.036 mg/m^3 (ECHA). [KI Score = 1].

In an OECD 403 (Acute Inhalation Toxicity) test and an EPA OTS 798.1150 (Acute Inhalation toxicity) test for decamethylcyclopentasiloxane (CAS RN 541-02-6), the LC_{50} after 4 hours was determined to be 0.00867 mg/m^3 (ECHA). [KI Score = 1].

There was no adequate data available for dodecamethylcyclohexasiloxane (CAS RN 540-97-6).

Dermal

An acute dermal LD_{50} value of > 2375 mg/kg bw was determined for octamethylcyclotetrasiloxane (CAS RN 556-67-2) using an OECD 402 (Acute Dermal Toxicity) test (ECHA) [KI Score = 2].

An acute dermal LD_{50} value of > 2,000 mg/kg bw was determined for decamethylcyclopentasiloxane (CAS RN 541-02-6) using an OECD 402 (Acute Dermal Toxicity) test (ECHA). [KI Score = 1].

An acute dermal LD_{50} value of > 2,000 mg/kg bw was determined for dodecamethylcyclohexasiloxane (CAS RN 540-97-6) using an OECD 402 (Acute Dermal Toxicity) test (ECHA). [KI Score = 1].

C. Irritation

Eye

In an OECD 405 (Acute Eye Irritation/Corrosion) test, octamethylcyclotetrasiloxane (CAS RN 556-67-2) did not induce eye irritation (ECHA). [KI Score = 1].

In an OECD 405 (Acute Eye Irritation/Corrosion) test, decamethylcyclopentasiloxane (CAS RN 541-02-6) did not induce eye irritation (ECHA). [KI Score = 1].

In an OECD 405 (Acute Eye Irritation/Corrosion) test, dodecamethylcyclohexasiloxane (CAS RN 540-97-6) did not induce eye irritation (ECHA) [KI Score = 1].

Skin

In an OECD 404 (Acute Dermal Irritation/Corrosion) test, octamethylcyclotetrasiloxane (CAS RN 556-67-2) did not induce skin irritation (ECHA) [KI Score = 2].

In an OECD 404 (Acute Dermal Irritation/Corrosion) test, decamethylcyclopentasiloxane (CAS RN 541-02-6) did not induce skin irritation (ECHA) [KI Score = 1].

In an OECD 404 (Acute Dermal Irritation/Corrosion) test, dodecamethylcyclohexasiloxane (CAS RN 540-97-6) did not induce skin irritation (ECHA) [KI Score = 1].

D. Sensitisation

Octamethylcyclotetrasiloxane (CAS RN 556-67-2) was not sensitising to the skin in an OECD 406 (Skin Sensitisation) test (ECHA) [KI Score = 1].

Decamethylcyclopentasiloxane (CAS RN 541-02-6) is not expected to be sensitising to the skin based on results from an OECD 429 (Skin Sensitisation Local Lymph Node Assay) study (ECHA) [KI Score = 1].

The OECD Test Guideline Study 406 found no indication of sensitisation potential for dodecamethylcyclohexasiloxane (CAS RN 540-97-6) (ECHA) [KI Score = 1].

E. Repeated Dose Toxicity

Oral

In two separate 14-day studies, octamethylcyclotetrasiloxane (CAS RN 556-67-2) (purity >98 %) in 0.5 % (w/v) methylcellulose vehicle was administered by gavage daily for two weeks to SD rats (8/sex/dose) at doses of 0, 25, 100, 400, or 1600 mg/kg bw/day or female NZW rabbits (n=6) at doses of 0, 500, or 1000 mg/kg bw/day. No overt signs of toxicity were observed in either species. Treatment-related effects in rats include decreased bodyweight at 1600 mg/kg bw/day (sex not specified) and increased liver weights in both sexes at 400 and 1600 mg/kg bw/day (SCCP, 2005; SCCS, 2010). Morphometric and electron microscopic examination of the liver showed that the increased liver weights were due to hepatocellular hyperplasia. All treated rabbits exhibited significant decreases in food consumption and bodyweight. Changes in the spleen and thymus were also observed in the rabbits but were reportedly not dose-dependent. A NOAEL was not established (NICNAS, 2020b). [Kl. Score = 4].

In a 28-day feeding study, octamethylcyclotetrasiloxane (as liquid drops encapsulated in a capsule composed of 80-90 % gelatine, 5 % modified cornstarch, and 15 % sucrose) was administered to SD rats (5/sex) in the diet. The dose level of the chemical was 2.1 % of the diet with an approximate daily intake estimated from 200 to 300 mg/kg bw/day. The chemical was fed to two groups, young and adult rats, with corresponding controls for each of the treatment groups. Reported clinical signs of toxicity include stress, rough fur and emaciation. Decreased food consumption and reduced bodyweight gain were observed. At necropsy, depleted body fat reserves and watery caecal contents were seen in the treated animals A NOAEL was not established (NICNAS, 2020b). [Kl. Score = 4].

Rats (unspecified strain) and rabbits (unspecified strain) administered the chemical at 500 mg/kg bw/day in the diet for 8 months (rats) and 12 months (rabbits) showed no effects of treatment. No other details were provided (NICNAS, 2020b).

In an OECD 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) study, Wistar rats were given decamethylcyclopentasiloxane (CAS RN 541-02-6) via oral gavage. The rats were treated for 13 weeks and observed for overt signs of toxicity. A NOAEL of 1,000 mg/kg bw/day was established due to histopathological changes (ECHA) [KI Score = 1].

In an OECD 422 (Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test) study, rats were administered dodecamethylcyclohexasiloxane CAS RN 540-97-6 via oral gavage for 28 days. A NOAEL of 1,000 mg/kg bw/day, the highest dose tested, was established due to systemic toxicity (ECHA) [KI Score = 1].

Inhalation

In a OCED Guideline 453 (Combined Chronic Toxicity/Carcinogenicity Studies) study, octamethylcyclotetrasiloxane (CAS RN 556-67-2) was administered to Fischer rats via whole body inhalation vapour for 24 months. A NOAEC of 150 ppm (1,820 mg/m^3) was established for general toxicity and local respiratory effects in the nasal cavity (ECHA). [KI Score = 1]

In an OECD 453 (Combined Chronic Toxicity/Carcinogenicity Studies) study, Fischer 344 rats were administered decamethylcyclopentasiloxane (CAS RN 541-02-6) via whole body inhalation vapour for up to 106 weeks. A NOEC for general toxicity was determined to be ≥160 ppm (2420 mg/m^3) based on local effects on the nasal cavity and adaptive increases in liver weights (ECHA) [KI Score = 1].

In an OECD Guideline 413 (Subchronic Inhalation Toxicity) study, Sprague Dawley rats were given dodecamethylcyclohexasiloxane (CAS RN 540-97-6) via whole body inhalation vapours for 90 days. Dodecamethylcyclohexasiloxane was found in the nasal tissues and in the livers and lungs of female rats. A NOAEL of 1 ppm (18.2 mg/m^3) was established based on permanent hyperplasia and inflammation of nasal tissues (ECHA). [KI Score = 1]

Dermal

In a three-week OECD 410 (Repeated Dermal Toxicity 21/28 Day) study, New Zealand White rabbits were exposed to octamethylcyclotetrasiloxane (CAS RN 556-67-2) and no adverse effects were observed. Therefore, the dermal NOAEL was determined to be ≥ 1 mL/kg-bw/day or 960 mg/kg bw/day (ECHA). [KI Score = 2]

In an OECD 410 (Repeated Dermal Toxicity 21/28 Day) study, Sprague Dawley rats were administered decamethylcyclopentasiloxane (CAS RN 541-02-6) for 28 days. No adverse effects were observed, a NOAEL of 1600 mg/kg bw/day was established (ECHA). [KI Score = 1]

There were no adequate Repeated Dermal Toxicity Studies available for dodecamethylcyclohexasiloxane (CAS RN 540-97-6). However, given the low dermal absorption of the chemical and the absence of serious systemic effects, repeated dermal exposure to the chemical is not expected to cause serious damage to health (NICNAS, 2020c).

F. Genotoxicity

The cyclic polyorganosiloxanes are not expected to be genotoxic.

In Vitro Studies

The majority of *in vitro* genotoxicity studies on cyclic polyorganosiloxanes indicated negative results including:

- bacterial reverse mutation assays (similar to OECD TG 471) in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538, and *Escherichia coli* WP2 uvrA strain with and without metabolic activation;
- bacterial DNA repair assay (similar to EPA OPPTS 870.5500) in E. coli polA+ strain with and without metabolic activation;
- DNA damage and mitotic recombination assay in *Saccharomyces cerevisiae* with and without metabolic activation;
- mammalian cell gene mutation test (similar to OECD TG 476) in mouse lymphoma cells, with and without metabolic activation;
- mammalian chromosome aberration test (similar to OECD TG 473) in Chinese hamster ovary (CHO) cells with and without metabolic activation;
- mammalian chromosome aberration test (similar to OECD TG 473) in mouse lymphoma cells) with and without metabolic activation;
- DNA damage and/or repair assays (sister chromatid exchange [SCE], unscheduled DNA synthesis (UDS) and alkaline elution) in L5178Y cells with and without metabolic activation;
- SCE assay in CHO cells, with and without metabolic activation; and
- DNA repair assay in Escherichia coli strain W3110, with and without metabolic activation (NICNAS, 2020b, 2020c and 2020d).

Octamethylcyclotetrasiloxane (CAS RN 556-67-2) was positive in a chromosomal aberration test in mouse lymphoma cells. Chromosomal aberrations were induced following metabolic activation and at the high dose only. No dose-response relationship was reported in this test (NICNAS, 2020b).

In Vivo Studies

In an OECD 475 (Mammalian Bone Marrow Chromosome Aberration Test) study, Sprague Dawley rats were exposed to octamethylcyclotetrasiloxane (CAS RN 556-67-2) via whole body inhalation. The results from this study showed that the substance is negative for clastogenicity/chromosome aberrations. In an OECD 478 (Genetic Toxicity: Rodent Dominant Lethal Test) study, Sprague Dawley rats were exposed to the substance via oral gavage for 8 weeks. The results from this study indicate that octamethylcyclotetrasiloxane does not induce chromosome damage in germ cells (ECHA). [Kl. Score = 2].

In an OECD Guideline 486 (Unscheduled DNA Synthesis UDS test with Mammalian Liver cells in vivo)study, Fischer 344 rats were exposed to decamethylcyclopentasiloxane (CAS RN 541-02-6) via whole body inhalation. The results from this study shown that the substance does not induce unscheduled DNA syntheses. In an OECD Guideline 474 test (Mammalian Erythrocyte Micronucleus Test), Fischer rats were exposed to the substance via whole body inhalation for 7 days. The results indicate that decamethylcyclopentasiloxane does not induce micronuclei in cells (ECHA). [KI Score = 1]

In an OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) study, ICR mice were exposed to dodecamethylcyclohexasiloxane (CAS RN 540-97-6) via intraperitoneal injections for 24 to 78 hours. The results from this study indicate that the substance does not induce micronucleation *in vivo* (ECHA). [KI Score = 1]

G. Carcinogenicity

Based on the available information summarised below, cyclic polyorganosiloxanes are not considered to be carcinogenic.

Oral

No available studies.

Inhalation

In a OCED Guideline 453 (Combined Chronic Toxicity/Carcinogenicity Studies) study, octamethylcyclotetrasiloxane (CAS RN 556-67-2) was administered to Fischer rats via whole body inhalation vapour for 24 months. Inhalation exposure to the substance induced an increased incidence of endometrial adenomas and cystic endometrial epithelial hyperplasia in the uteri of female Fischer 344 rats exposed to 700 ppm for 24 months. There were no carcinogenic findings in male rats. The study authors indicated the NOAEL for carcinogenic effects was 150 and ≥700 ppm in females and males, respectively. However, based on fundamental differences between rats and humans with respect to the development of reproductive function, brain regulation of LH secretion, and the mechanism of reproductive aging and the hormonal environment of reproductive senescence the NOAEC for carcinogenic effects relevant to humans is ≥700 ppm (equivalent to ≥8492 mg/m^3 based on a molecular weight of 296.62) (ECHA). [Kl. Score = 1].

In an OECD 453 (Combined Chronic Toxicity/Carcinogenicity Studies) study, Fischer 344 rats were administered decamethylcyclopentasiloxane (CAS RN 541-02-6) via whole body inhalation vapour for up to 106 weeks. The NOAEC for carcinogenic effects was determined to be 160 ppm (2420 mg/m^3), the highest dose tested. There were no treatment-related effects on survival, body weight, ophthalmological parameters, haematology, clinical chemistry and urinalysis parameters in any of the groups. Non-neoplastic changes included increased incidence of hyaline inclusions in the nasal olfactory epithelium and increased liver weights at the highest concentration only. In females exposed to the highest concentration, there was a significantly increased incidence of endometrial adenocarcinoma. Endometrial adenomatous polyps and endometrial adenocarcinoma were also increased in females from the recovery group. Obligatory preceding lesions to these uterine neoplasms were not observed in these animals, e.g. uterine adenoma or endometrial hyperplasia. The mechanism by which the endometrial adenocarcinomas occur in F344 rats may be related to dopamine agonist activity of the chemical, leading to hormonal dysregulation that can stimulate the development and progression of these tumours (NICNAS, 2020d). These imbalances are common in rodents and are of no relevance to humans (ECHA). [Kl. Score = 1].

There are no adequate studies available for dodecamethylcyclohexasiloxane (CAS RN 540-97-6). No animal data are available for the chemical. Based on the information available from the genotoxicity studies and Quantitative Structure Activity Relationship (QSAR) modelling, the chemical is not expected to be carcinogenic (NICNAS, 2020c).

Dermal

No available studies.

H. Reproductive Toxicity

Octamethylcyclotetrasiloxane is considered to cause reproductive toxicity following inhalation exposure. Decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane are not considered to be reproductive toxicants.

A NOAEC of 300 ppm (3640 mg/m^3) was determined for reproductive toxicity in a two-generation reproductive study (OECD 416) using Sprague-Dawley rats exposed to octamethylcyclotetrasiloxane (CAS RN 556-67-2) via whole body inhalation. The animals were dosed as follows 70 ppm, 300 ppm, 500 ppm and 700 ppm. This NOAEC is based on reduced female fertility indices and reduced mean live litter sizes (ECHA). [KI Score = 1].

A NOAEL of at least 160 ppm was determined for reproductive toxicity in a two-generation reproductive toxicity study (EPA OPP 83-6 and EPA OPPTS 870.3800) in Sprague-Dawley rats exposed to decamethylcyclopentasiloxane (CAS RN 541-02-6) via whole body inhalation at exposure concentrations of 30, 70 and 160 ppm. Overall, there was no evidence of parental toxicity, reproductive toxicity, neonatal toxicity, or developmental neurotoxicity (ECHA). [KI Score = 1].

In an OECD 422 (Combined Repeated Dose Toxicity Study with Reproduction/Developmental Toxicity Screening Test) study Sprague Dawley rats were administered dodecamethylcyclohexasiloxane (CAS RN 540-97-6) via oral gavage for 28 days. A NOAEL of ≥ 1,000 mg/kg/day, highest dose tested, was established due to no clear effect on reproductive toxicity in the screening study (ECHA) [KI Score = 1].

I. Developmental Toxicity

None of the substances are considered to be developmental toxicants.

An OECD 414 (Prenatal Developmental Toxicity Study) was performed on New Zealand White rabbits exposed to octamethylcyclotetrasiloxane (CAS RN 556-67-2) via whole body inhalation [KI Score = 1]. The animals were dosed as follows: 100 ppm, 300 ppm and 500 ppm. The substance did not affect foetal development and the NOAEL for this endpoint was therefore greater than the highest concentration tested (500 ppm or 6,066 mg/m^3). The NOAEC for maternal toxicity was 300 ppm (3,640 mg/m^3) based on reduced food consumption in the highest dose group (ECHA). [Kl. Score = 1].

An OECD 414 (Prenatal Developmental Toxicity Study) study was performed on Sprague Dawley rats administered decamethylcyclopentasiloxane (CAS RN 541-02-6) via whole body inhalation. A NOAEC of 161 ppm (2,427 mg/m^3), highest dose tested, was established for maternal toxicity and developmental toxicity as there were no adverse effects reported in this study (ECHA). [KI Score = 1]

An OECD 414 (Prenatal Developmental Toxicity Study) study was performed on Wistar Han rats exposed to administered dodecamethylcyclohexasiloxane (CAS RN 540-97-6) via oral gavage. The maternal and developmental NOAEL was determined to be 1,000 mg/kg bw/day, highest dose tested, based on no adverse effects (ECHA). [Kl. Score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for cyclic polyorganosiloxanes follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non Cancer

The lowest NOAEL reported in repeat dose toxicity studies is 1,000 mg/kg bw/day for decamethylcyclopentasiloxane (CAS RN 541-02-6) and dodecamethylcyclohexasiloxane (CAS RN 540-97-6). This value is lower than the NOAEC derived for reproductive toxicity via inhalation exposures from the inhalation combined chronic toxicity and carcinogenicity study conducted for octamethylcyclotetrasiloxane (CAS RN 556-67-2) and corrected for repeated dose systemic effects via the oral route (NOAEL of 2,990 mg/kg bw/day). The NOAEL of 1,000 mg/kg bw/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value for the cyclic polyorganosiloxanes.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1
Oral RfD = 1000/(10 x 10 x 1 x 1 x 1) = 1000/1000 = <u>1 mg/kg/day.</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

The substances are not considered carcinogens. Thus, a cancer reference value will not be calculated.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

Octamethylcyclotetrasiloxane is flammable but is not oxidising or explosive.

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Substances in this category tend to have low water solubility, high adsorption and partition coefficients and slow degradation rates in the sediment compartment. For substances with a log K_{ow} of 8 and above (decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane), no long-term toxicity effects are seen with aquatic organisms due to the low water solubility limiting the bioavailability and uptake of the substance. While octamethylcyclotetrasiloxane has exhibited toxicity to water column organisms in the laboratory, it is not toxic up to its limits of functional water solubility under realistic environmental conditions. In the environment, the substances will adsorb to particulate matter and will partition to soil and sediment compartments.

B. Aquatic Toxicity

The high volatility from water and the very high hydrophobicity of chemicals in this group has presented challenges for the conduct of standard short- and long-duration aquatic toxicity tests. In an attempt to ensure consistent exposures of test organisms to these chemicals, some aquatic toxicity tests have been conducted in fully enclosed systems with no head-space. These tests, which are summarized below, indicate no toxic effects on aquatic life up to the limit of their respective

solubilities in water. Some toxic effects have been observed for octamethylcyclotetrasiloxane under optimised aquatic exposure conditions which indicate that these chemicals have a non-polar narcosis mode of toxic action (MOA) in aquatic organisms. These MOA effects are, therefore, expected to be both reversible and dependent on the kinetics of uptake and elimination by aquatic life (NICNAS, 2020a).

The rate of uptake from water is known to be a significant factor influencing both the toxicity and bioconcentration of very hydrophobic neutral chemicals. Recent modelling of the uptake of cyclic volatile methyl siloxanes from water by fish suggests that the time required for adult fish to achieve the assumed narcotic critical body residue associated with a 50% effect on the organism (CBR = 3 millimoles per kilogram) is 24.7 days for octamethylcyclotetrasiloxane, 101 days for decamethylcyclopentasiloxane and 397 days for dodecamethlcyclohexasiloxane; these calculations assume continuous exposure at the respective water solubility limits for each chemical and no metabolism of the chemicals. These findings are significant for ecological risk assessment as they suggest that significant acute toxic effects are unlikely to occur as a result of exposure to these chemicals in the water column because this would require unfeasibly long exposures at concentrations that are a significant fraction of the saturation concentration of each chemical. It also provides further evidence that exposure through aquatic food-chains will provide a more environmentally significant exposure pathway for these very hydrophobic chemicals (NICNAS, 2020a).

Acute Studies

Tables 2, 3 and 4 list the results of acute aquatic toxicity studies conducted on the three cyclic polyorganosiloxanes.

Table 2: Acute Aquatic Toxicity Studies on Fish for Cyclic Polyorganosiloxanes

	Octamethyl cyclotetrasiloxane CAS RN 556-67-2	**Decamethyl cyclopentasiloxane CAS RN 541-02-6**	**Dodecamethyl cyclohexasiloxane CAS RN 540-97-6**
Test Species	*Oncorhynchus mykiss* (Rainbow trout)	*Oncorhynchus mykiss* (Rainbow trout)	No data*
Endpoint	96-hour LC_{50}	96-hour LC_{50}	-
Results (mg/L)	> 0.022 mg/L	> 0.016 mg/L	-
Klimisch score	2	1	-
Reference	ECHA	ECHA	-

Table 3: Acute Aquatic Toxicity Studies on Invertebrates for Cyclic Polyorganosiloxanes

	Octamethyl cyclotetrasiloxane CAS RN 556-67-2	**Decamethyl cyclopentasiloxane CAS RN 541-02-6**	**Dodecamethyl cyclohexasiloxane CAS RN 540-97-6**
Test Species	*Daphnia magna*	*Daphnia magna*	No data*
Endpoint	48-hourEC_{50}	48-hour EC_{50}	-
Results (mg/L)	> 0.015 mg/L	> 0.0029 mg/L	-
Klimisch score	1	1	-
Reference	ECHA	ECHA	-

Table 4: Acute Aquatic Toxicity Studies on Algae for Cyclic Polyorganosiloxanes

	Octamethyl cyclotetrasiloxane CAS RN 556-67-2	**Decamethyl cyclopentasiloxane CAS RN 541-02-6**	**Dodecamethyl cyclohexasiloxane CAS RN 540-97-6**
Test Species	*Pseudokirchneriella subcapitata*	*Pseudokirchneriella subcapitata*	*Pseudokirchneriella subcapitata*
Endpoint	96-hour LC_{50}	96-hour LC_{50}	72-hour EC_{50}
Results (mg/L)	> 0.022 mg/L	> 0.012 mg/L	> 0.002 mg/L
Klimisch score	1	1	1
Reference	ECHA	ECHA	ECHA

*Short-term toxicity tests are not needed because a long-term aquatic toxicity study is available. (ECHA).

Chronic Studies

Fish: A 93-day study was conducted to determine the toxicity of octamethylcyclotetrasiloxane (CAS RN 556-67-2) to Rainbow trout (*Oncorhynchus mykiss*). The NOAEC was determined to be ≥0.004 mg/L based on embryo viability, hatching success, larval survival and growth during early life stages However, to better define the potential NOEC, modelling (Mackay et al., 2015) to estimate fish critical body burden (CBB) levels and compare those CBB levels to those associated with a narcotic MOA, under which this substance and other volatile methyl siloxanes materials are proposed to operate was conducted. These results indicate that the substance dose levels up to 12 µg/l could have been successfully used in the 93-day trout study without adverse effect (ECHA). [KI Score = 2].

A 90-day (60 days post hatch) study was conducted to determine the toxicity of decamethylcyclopentasiloxane (CAS RN 541-02-6) Rainbow trout (*Oncorhynchus mykiss*). The NOAEC was determined to be ≥0.014 mg/L based on hatching, larval survival and growth (ECHA). [KI Score = 1].

Read across of decamethylcyclopentasiloxane (CAS RN 541-02-6) was used to determine the toxicity of dodecamethylcyclohexasiloxane (CAS RN 540-97-6). The NOAEC was determined to be ≥0.014 mg/L based on hatching, larval survival and growth in rainbow trout (ECHA). [KI Score = 2]Invertebrates: A 21-day study was conducted to determine the toxicity of octamethylcyclotetrasiloxane (CAS RN 556-67-2) to *Daphnia magna*. A NOEC of 0.0079 mg/L was determined for this substance based on survival (ECHA). [KI Score = 1]

A 21-day study was conducted to determine the toxicity of Decamethylcyclopentasiloxane (CAS RN 541-02-6). A NOEC of ≥0.015 mg/L was established based for *Daphnia magna* based on survival, reproduction and growth (ECHA). [KI Score = 1]

A 21-day study was conducted to determine the toxicity of dodecamethylcyclohexasiloxane (CAS RN 540-97-6) to *Daphnia magna* was conducted according to OECD Test Guideline 211 in sealed containers. A NOEC of ≥0.0046 mg/L was determined based on survival, growth and reproduction (ECHA). [KI Score = 1]

Algae: A static closed bottle test with P. subcapitata conducted according to OECD TG 201 showed no treatment related inhibition of growth and yield of green algae (relative to the solvent control) after 72 hours of exposure to dodecamethylcyclohexasiloxane at the highest measured exposure concentration (2.0 µg/L). A NOEC of 0.002 mg/L was determined. The highest exposure concentrations utilised in the short- and long-term tests were close to the functional solubility of the test substance in the exposure media. It is therefore concluded that the substance is not toxic to

fish, invertebrates and algae following short- and long-term exposure at its functional water solubility limit (ECHA). [KI Score = 1].

C. Sediment Toxicity

The chemicals in this group are expected to have low toxicity to benthic invertebrates (NICNAS, 2020a).

The 28-day no observed effect concentration (NOEC) for Oligochaete (*Lumbriculus variegatus*) exposed to octamethylcyclotetrasiloxane (CAS RN 556-67-2) is 13 mg/kg dry weight (ECHA) [KI score = 1].

The 28-day NOEC for *Chironomus riparius* exposed to decamethylcyclopentasiloxane (CAS RN 541-02-6) is 70 mg/kgdry weight (ECHA) [KI score = 1].

A read across study of results for decamethylcyclopentasiloxane was conducted to derive the 28-day NOEC of 130 mg/kgdry weight (135 mg/kg dry weight normalised to 5% OC) for dodecamethylcyclohexasiloxane (CAS RN 540-97-6) in *Hyalella azteca* (ECHA). [KI score = 2].

D. Terrestrial Toxicity

Terrestrial studies with siloxanes are considered to be difficult to conduct due to their high volatilisation potential (high HLC) and the potential for degradation in soil (ECHA). However, studies were available for decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane.

In an OECD Test Guideline 222 study, a 28-day LC_{50} value of >4074 mg/kg dry weight and a 56-day NOEC of ≥4074 mg/kg dry weight have been determined for the effects of decamethylcyclopentasiloxane (CAS RN 541-02-6) on mortality, and on reproduction and growth, respectively of the earthworm, *Eisenia andrei* (ECHA). [KI Score = 2]. T

A 56-day earthworm reproduction test for dodecamethylcyclohexasiloxane (CAS RN 540-97-6), at concentrations up to 1000 mg/kg soil dry weight, has been conducted in accordance with OECD TG 222 (earthworm reproduction test) and in compliance with GLP. No effects on survival or reproduction were observed. Based on the findings of the test, a 28-day NOEC value of ≥1000 mg/kg dry weight (highest concentration tested) was determined for the effects of the test substance on growth of adult earthworms, based on nominal concentrations. A 56-day NOEC value of ≥1000 mg/kg dry weight (highest concentration tested) was determined for the effects of on reproduction of the earthworm, based on nominal concentrations (ECHA). [KI Score = 2].

E. Calculation of PNEC

The PNEC calculations for cyclic polyorganosiloxanes follow the methodology discussed in DEWHA (2009).

<u>PNEC water</u>

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (> 0.015 mg/L), *Daphnia* (> 0.0029 mg/L) and algae (> 0.002 mg/L). There are long-term studies available for fish (≥ 0.012 mg/L), *Daphnia* (≥ 0.0046 mg/L) and invertebrates (> 0.002 mg/L). Before identifying an applicable effect concentration for the PNEC calculation, it is appropriate to consider that aquatic fate characteristics of the cyclic polyorganosiloxanes and how test conditions can

impact the findings of the toxicity studies. For example, the lowest NOEC value reported for algael inhibition (0.002 mg/L) was determined using a closed test system. As one of the cyclic polyorganosiloxanes (octamethylcyclotetrasiloxane) is highly volatile and rapidly hydrolyzes, this NOEC does not appear to be appropriate. Likewise, for the chronic invertebrate study. On the basis of the short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 0.012 mg/L for fish. This NOEC values is lower (and more conservative) than the maximum achievable solubility of octamethylcyclotetrasiloxane (0.015 mg/L) used in the derivation of the PNEC for that substance by ECHA. The $PNEC_{water}$ is 0.0012 mg/L.

PNEC sediment

Siloxanes are expected to partition more readily to the sediment phase rather than the aquatic phase. No adverse effects were observed in any of the chronic studies on sediment-dwelling organisms. Experimental results are available for three sediment dwelling organisms. The lowest NOEC, which was observed in the study using Oligochaete (*Lumbriculus variegatus*), was 13 mg/kg dw. Using an assessment factor of 50, the $PNEC_{sediment}$ was determined to 0.26 mg/kg.

PNEC soil

Terrestrial studies with siloxanes are considered to be difficult to conduct due to their high volatilisation potential (high HLC) and the potential for degradation in soil (ECHA). However, studies were available for decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane. Experimental results are available for one tropic level. The lowest NOEC was observed in the study using earthworms (*Eisenia andrei*), and was 1,000 mg/kg dw. Using an assessment factor of 100, the $PNEC_{soil}$ was determined to 10 mg/kg.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Cyclic polyorganosiloxanes are not readily biodegradable in sediments. They have half-lives in excess of 1 year. Thus, they meet the screening criteria for persistence.

Based on measured BCF values in fish, which are greater than 2000 L/kg, both octamethylcyclotetrasiloxane and decamethylcyclopentasiloxane have a high potential to bioaccumulate. Thus, meeting the screening criteria for bioaccumulation. However, dodecamethylcyclohexasiloxane has a BCF value in fish of 1,160 mg/L. Thus, it does not meet the screening criteria for bioaccumulation..

The chronic toxicity data on the cyclic polyorgansiloxanes show NOECs < 0.1 mg/L. The acute LC_{50} values are also less than 1 mg/L. Thus, meeting the screening criteria for toxicity. However, for octamethylcyclotetrasiloxane, a classification of toxicity is uncertain as the observed toxic effects on aquatic life below the water solubility limit for this chemical were obtained under exposure conditions which may not be relevant to the ecological hazards of this chemical. Likewise, for decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane, no toxic effects on aquatic life were observed up to their respective water solubility limits.

The overall conclusion is that octamethylcyclotetrasiloxane is a PBT substance (with uncertainty) and that decamethylcyclopentasiloxane and dodecamethylcyclohexasiloxane are not PBT substances. Octamethylcyclotetrasiloxane has been identified as a PBT substance by the European Union (EU).

IX. CLASSIFICATION AND LABELLING

A. Classification

Octamethylcyclotetrasiloxane (CAS RN 556-67-2):

- H361: Suspected of damaging fertility or the unborn child.
- H361f: Suspected of damaging fertility.

Decamethylcyclopentasiloxane (CAS RN 541-02-6):

- H227: Combustible liquid.
- H413: May cause long lasting harmful effect to aquatic life.

Dodecamethylcyclohexasiloxane (CAS RN 540-97-6):

- H227: Combustible liquid.

B. Labelling

Warning Flammable liquids

C. Pictogram



Octamethylcyclotetrasiloxane

X. SAFETY AND HANDLING

Refer to the product SDS for additional information and confirmation of the information provided herein.

A. First Aid

Eye Contact

In the case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for any of the members of this group.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing closed work clothing is recommended.

F. Transport Information

Not regulated for transport.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

National Industrial Chemicals Notification and Assessment Scheme [NICNAS]. (2020a). Cyclic volatile methyl siloxanes: Environment tier II assessment. June 16, 2020.

NICNAS. (2020b). Cyclotetrasiloxane, octamethyl-: Human health tier II assessment. July 1, 2016.

NICNAS. (2020c). Cyclohexasiloxane, dodecamethyl-: Human health tier II assessment. July 1, 2016.

NICNAS. (2020d). Cyclopentasiloxane, decamethyl-: Human health tier II assessment. June 30, 2017.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

DIAMMONIUM PEROXODISULPHATE

This dossier on diammonium peroxodisulphate presents the most critical studies pertinent to the risk assessment of diammonium peroxodisulphate in its use in drilling muds. It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Diammonium peroxodisulphate

CAS RN: 7727-54-0

Molecular formula: $H_8N_2O_8S_2$

Molecular weight: 228.21 g/mol

Synonyms: Diammonium peroxydisulfate; Diammonium peroxydisulphate; Diammonium persulfate; Peroxydisulfuric acid (((HO)S(O)2)2O2), ammonium salt (1:2); Peroxydisulfuric acid (((HO)S(O)2)2O2), diammonium salt; Peroxydisulfuric acid, diammonium salt; ammonium persulphate

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diammonium Peroxodisulphate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odourless, crystalline solid	1	ECHA
Melting Point	ND. Decomposes at ca. 393 K (= 120°C) at 100.66 kPa	1	ECHA
Boiling Point	ND. Decomposes at ca. 393 K (= 120°C) at 100.79 kPa	1	ECHA
Density	1260 kg/m³ at 20°C	1	ECHA
Vapour Pressure	0 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	Not applicable as substance is inorganic	-	ECHA
Water Solubility	850 g/L @ 25°C	2	ECHA
Viscosity	ND. Substance is a solid at room temperature	-	ECHA
Dissociation constant (pKa)	Diammonium persulfate dissociates completely to ammonium cation and persulfate anion when it is dissolved in water.	-	ECHA
Flammability	Non-flammable	1	ECHA

ND – not determined

Diammonium peroxidisulphate is widely used in cosmetics and personal care products, perfumes and fragrances, adhesives and sealants, anti-freeze products, coating products, fillers, putties, plasters, modelling clay, non-metal-surface treatment products, inks and toners, leather treatment products, lubricants and greases, polishes and waxes and textile treatment products and dyes.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Diammonium peroxodisulphate dissociates in aqueous media to the ammonium cation and persulfate anion. Biodegradation is not applicable to inorganic compounds. Diammonium peroxodisulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Diammonium peroxodisulphate is not expected to adsorb to soil or sediment because of its dissociation properties and high water solubility.

B. Partitioning

Persulfates dissociate in water to the corresponding cation and persulfate anion. Hydrolysis is temperature and pH dependent. The persulfate anion, independent from the cation, undergoes decomposition in normal water or acid conditions, readily oxidising water to oxygen, producing acid conditions. All degradation products are ubiquitous to the environment (ECHA).

Diammonium peroxodisulphate was shown to be hydrolytically stable at 10°C and pH 4, 7 and 9, a minor hydrolysis was observed at 25°C, whereas a very strong hydrolysis at 60°C was observed within four days. The DT50 at pH 4 and 60°C was determined to be 27.2 h, at pH 7 and 9 and 60°C the DT50 was determined to be 36.5 h. The DT50 at environmentally relevant temperature (12°C) and pH 7 was extrapolated to be 1698.18 h (70.76 d) (ECHA) [Kl. Score = 1].

C. Biodegradation

Biodegradation is not applicable to inorganic compounds.

D. Environmental Distribution

No experimental data are available for diammonium peroxodisulphate. Persulfates are soluble in water and their vapour pressures are negligible. Thus, persulfates released into the environment are distributed into the water compartment in ionic form of the cation and persulfate ion. Persulfates are not expected to sorb to soil due to their dissociation properties, instability (hydrolysis) and high water solubility. They behave as free ions and decompose into sulfate and bisulfate ions. All decomposition products are ubiquitous in the environment (ECHA).

E. Bioaccumulation

There are no bioaccumulation studies on diammonium peroxodisulphate. Substances of the persulfate category are inorganic salts sharing the same anionic persulfate moiety. Persulfates are very soluble in water and are not expected to bioaccumulate in soil or aqueous solutions. They will decompose into organic sulfate or bisulfate (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Diammonium peroxodisulphate is irritating to the eyes, skin and respiratory tract. Inhalation of dust may cause asthma-like reactions. Repeated or prolonged contact may cause skin sensitisation. In a 90-day oral toxicity study in rats, systemic effects (intestinal changes) were observed at the highest dose (200 mg/kg bw/day). It is not carcinogenic or genotoxic, nor does the substance show evidence of reproductive or developmental toxicity.

B. Toxicokinetics/Metabolism

Persulphates are inorganic salts that decompose on heating without a definite melting point at temperatures above 100°C. Due to their properties as inorganic salts and considering their low vapour pressures, an exposure via inhalation is not very likely. Absorption by the skin is also not very likely. Generally, salts largely do not penetrate the skin. Persulphate salts rapidly hydrolyse upon contact with water or water vapour. As a result, persulphates will rapidly degrade and will eventually form the corresponding cations (ammonium, potassium, sodium) and persulphate anions. The persulphate anion, independent of the cation, undergoes further decomposition upon contact with water to form sulphate species. Based on these fundamental properties of persulphates, they are not likely to become bioavailable by inhalation, ingestion or contact by skin.

C. Acute Toxicity

Diammonium persulfate was tested for acute toxicity via the oral, dermal and inhalation routes in rats. In an acute oral toxicity study LD_{50} and LD_0 values of 742 mg/kg bw and 300 mg/kg bw, respectively, in the male rat and LD_{50} value of 700 mg/kg bw in the female rat were determined. In an acute dermal toxicity study LD_{50} and LD_0 values of greater than 2000 mg/kg bw and 2,000 mg/kg bw were determined, respectively. In an acute inhalation toxicity study (whole body exposure) LC_{50} and LC_0 values of greater than 2.95 mg/L and 2.95 mg/L, respectively, were determined.

D. Irritation

Diammonium peroxodisulphate is slightly irritating to the eye and skin of rabbits. Studies in humans indicate that aqueous solutions of 5% persulphate or higher can cause skin irritation.

E. Sensitisation

Results of animal skin sensitisation tests were negative when persulphate was applied topically but were positive when persulphate was injected intradermally. Repeated or prolonged contact may cause skin sensitisation.

F. Repeat Dose Toxicity

In a repeated dose 90-day oral toxicity study in rats (OECD Guideline 408), rats were fed three levels of test material, sodium persulphate (0, 300, 1000 and 3,000 ppm). On day 48 of the study, the concentration of the group receiving 1,000 ppm was increased to 5,000 ppm for the remainder of the study. The body weight of the rats in the two highest dose groups decreased during the last six weeks of treatment. There were no significant differences seen among the groups in urine analytical parameters, haematological blood parameters or both organ weight and body weight ratios. All rats survived the study. Intestinal changes were noted in rats which received 3,000 ppm of sodium persulfate for 13 weeks. These changes were seen more frequently among females than males. The

former received 50 percent more test material than the latter on a dose per body weight basis. No significant changes were seen among the controls or the groups which received 300 ppm, or 1,000 ppm in the diet for eight weeks, followed by 5,000 ppm in the diet for the remainder of the study. No other microscopic changes were noted on comparison among these three groups. LOAEL and NOAEL values of 200 and 91 mg/kg bw/day (3,000 and 1,000 ppm), respectively were determined.

G. Genotoxicity

Diammonium persulphate did not show any mutagenic effects in a bacterial reverse mutation assay.

H. Carcinogenicity

Diammonium persulphate of the persulphate category was tested for its skin carcinogenic potential in a 51-week dermal study with mice following a guideline similar to OECD Guideline 451. Based on the data obtained, diammonium persulphate was not considered carcinogenic. Diammonium peroxidisulphate is not listed in the Chemical Carcinogenesis Research Information System (CCRIS) or International Agency for Research on Cancer (IARC) databases or documented by USEPA as carcinogenic.

I. Reproductive/Developmental Toxicity

Diammonium persulphate was tested for oral reproductive/developmental toxicity in a screening test with rats according to OECD Guideline 421. No test substance-related effects were observed in P and F1 generations. A NOAEL value of 250 mg/kg/day for parental toxicity, reproduction parameters and developmental toxicity was determined. Dose levels were chosen based on the acute lethality studies for the ammonium salt and on a 90-day repeat-dose study in rats with the sodium salt (high dose: 225 mg/kg/day). In the developmental/reproduction study, animals were dosed prior to and during mating through gestation until lactation day 4. There was a transient depression in pup body weight at the 250 mg/kg dose level on lactation day 0 which resolved by lactation day 4. This effect was not considered adverse. Based on the available data, the persulphates do not show evidence of reproductive or developmental toxicity. The NOAEL is 250 mg/kg/day.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diammonium peroxidisulphate follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021). There are no existing drinking water guideline values for ammonium ions.

A. Non-cancer

The substance will readily disassociate to its respective cations and anions. As noted above, there are no drinking water guidelines for ammonium ions as there is insufficient data to set a guideline value based on health considerations. The Australian Drinking Water Guideline value for sulphate may apply to sulphate ions (500 mg/L for health and 250 mg/L for taste aesthetic threshold). An ammonia guideline based on aesthetics is however 0.5 mg/L and will be used as drinking water guideline for this dossier.

B. Cancer

A cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diammonium peroxidisulphate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Diammonium peroxodisulphate is of low toxicity concern to aquatic and terrestrial organisms.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on diammonium peroxodisulphate.

Table 2: Acute Aquatic Toxicity Studies on Diammonium Peroxodisulphate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hour LC_{50}	76.3 mg/L	1	ECHA
Daphnia magna	48-hour EC_{50}	120 mg/L	1	ECHA
Phaeodactylum tricornutum	72-hour EC_{10}	320 mg/L	1	ECHA

Chronic Studies

Long-term toxicity testing to fish was considered scientifically unjustified, due to the results obtained in the short-term toxicity to fish studies, the substance's physical-chemical properties and hydrolysis behaviour (ECHA).

An OECD Guideline 211 (Daphnia magna reproduction test) was performed and yielded a 21-day NOEC of 20.8 mg/L based on reproduction (ECHA) [Kl Score = 1].

C. Terrestrial Toxicity

No terrestrial toxicity studies are available.

Persulfates are not expected to be distributed into the terrestrial compartment and consequently not expected to cause toxicity to terrestrial organisms and plants (ECHA).

D. Calculation of PNEC

$PNEC_{water}$

Experimental results are available for three trophic levels. Acute EC_{50} values are available for fish (76 mg/L), Daphnia (120 mg/L) and algae (84 mg/L). On the basis that the data consists of short-term

results from three trophic levels, an assessment factor of 1,000 has been applied to the lowest reported effect concentration of 76 mg/L for fish. $PNEC_{water}$ is 0.076 mg/L.

$PNEC_{sediment}$

No experimental toxicity data on sediment organisms are available. Diammonium peroxydisulphate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} do not readily apply to inorganics, such as diammonium peroxidisulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on these properties, no adsorption of diammonium peroxydisulphate to sediment is to be expected.

$PNEC_{soil}$

No experimental toxicity data on terrestrial organisms are available. The environmental distribution of diammonium peroxydisulphate is dominated by its water solubility. Sorption of diammonium peroxydisulphate should probably be regarded as a reversible situation, i.e., the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as diammonium peroxidisulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, diammonium peroxydisulphate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diammonium peroxodisulphate is an inorganic salt that dissociates to respective cations and anions. Biodegradation is not applicable to these inorganic ions. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Diammonium peroxodisulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Thus, the substance does not meet the screening criteria for bioaccumulation.

Chronic aquatic toxicity data is > 0.1 mg/L and acute aquatic toxicity data is >1 mg/L. Thus, diammonium peroxodisulphate does not meet the screening criteria for toxicity.

The overall conclusion is that diammonium peroxodisulphate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H272: May intensify fire; oxidiser.

H302: Harmful if swallowed.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335: May cause respiratory irritation.

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Separate eyelids with fingers. Get medical attention.

Skin Contact

Remove contaminated clothing and shoes. Wash skin thoroughly with soap and water. Get medical attention.

Inhalation

If inhaled, remove from area to fresh air. Lay down quietly in recovery position. If breathing is difficult, give artificial respiration with breathing bag. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: sulphur oxides, nitrogen oxides, toxic pyrolysis products.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove. Avoid dust formation. Store in closed containers and dispose of in accordance with federal, state and local regulations. Clean up spill area and treat as special waste.

D. Storage and Handling

General Handling

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust. Take off contaminated clothing and shoes. Wash thoroughly after handling. Do not eat, drink or smoke during work.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids, or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for ammonium persulphate in Australia is 0.01 mg/m^3 as a peak exposure. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Ensure adequate ventilation. Localised ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment

Respiratory Protection: Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Wear suitable protective goggles (tightly fitting). Also wear face protection if there is a splash hazard. Ensure that eyewash stations and safety showers are close to the workstation location.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible. Remove and wash contaminated clothing before re-use. Contaminated work clothing should not be allowed out of the workplace.

F. Transport Information

UN1444 AMMONIUM PERISULPHATE

Class: 5.1

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol, Pharmacol. 25:1-5.

DICOCO DIMETHYL QUATERNARY AMMONIUM CHLORIDE

This dossier on dicoco dimethyl quaternary ammonium chloride (DQAC) (CAS RN 61789-77-3) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. For the purposes of this dossier, a surrogate substance of like composition (Quaternary ammonium compounds, coco alkyltrimethyl, chlorides) (CAS RN 61789-18-2) was evaluated. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Quaternary ammonium compounds, dicoco alkyldimethyl, chlorides

CAS RN: 61789-77-3

Molecular formula: $C_{26}H_{56}ClN$ (representative, UVCB substance)

Molecular weight: 418.18 g/mol (representative, UVCB substance)

Synonyms: dicoco dimethyl quaternary ammonium chloride; DQAC; dicocodimonium chloride; Quaternium-34; bis(coconut oil alkyl)dimethylammonium chloride

SMILES: CCCCCCCCCCCC[N+](CCCCCCCCCCCC)(C)(C).[Cl-] (representative, UVCB substance)

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of DQAC[1]

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Amorphous wax-like oyster white solid	1	ECHA
Melting Point	No melting point could be determined, as the test substance undergoes decomposition before melting at a temperature >160°C	1	ECHA
Boiling Point	No boiling point could be determined as the test substance undergoes decomposition before boiling at >160°C.	1	ECHA
Density	935 kg/m³ at 20°C	1	ECHA
Vapour Pressure	0.002 Pa at 25°C	1	ECHA
Partition Coefficient (log K_{ow})	2.39 at 20°C	1	ECHA
Water Solubility	1 g/L at 20°C	1	ECHA

Property	Value	Klimisch score	Reference
Flash Point	Flash point is only relevant to liquids and low melting point solids	1	ECHA
Auto flammability	No self-ignition temperature was observed up to the maximum temperature of 405°C	1	ECHA
Viscosity	30.2 mm^2/s at 20°C	1	ECHA

1 – Data taken from testing on the surrogate quaternary ammonium compounds, coco alkyltrimethyl, chlorides (Coco TMAC, CAS RN 61789-18-2)

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

DQAC is readily biodegradable, is unlikely to bioaccumulate, and has the potential to bind to soils and sediments. Details of supporting studies are provided below.

B. Biodegradation

An OECD Guideline 301 D (Ready Biodegradability: Closed Bottle Test) was performed on DQAC. The test substance at 3 mg/L was incubated with sludge from activated sludge plant treating predominantly domestic waste and O_2 consumption was determined over a period of 28 days. The biodegradation was calculated as the ratio of the biochemical oxygen demand to the theoretical oxygen demand. The test substance reached a biodegradation of 75% at Day 28. Therefore, DQAC is considered readily degradable (ECHA) [KI Score = 2].

C. Environmental Distribution

An OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) was performed on three soils and read across the quaternary ammonium salts (QAS) category. The experimentally-determined mead K_{oc} value of 1,640,329 L/kg is read across from QAS category substance. DQAC is expected to show a similar behaviour in soil (ECHA) [KI Score = 2].

D. Bioaccumulation

No data were available for bioaccumulation of DQAC. However, based on the low log K_{ow} of 2.39, substantial bioaccumulation is not expected (ECHA) [KI Score = 2].

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

DQAC has low acute toxicity by the oral and dermal routes. This substance was determined to be severely irritating to the skin and causes irreversible effects on the eyes. No systemic effects were observed in repeated dose oral or dermal toxicity studies. It is not genotoxic and is not expected to be a developmental toxicant.

B. Acute Toxicity

Oral

An OECD Guideline 401 (Acute Oral Toxicity) was performed. The study was conducted to determine the acute oral toxicity of the test substance in Sprague-Dawley rats according to OECD 401 and USEPA OPP 81-2 Guidelines, in compliance with GLP. Groups of 10 fasted animals (5 males and 5 females per dose except for 5 males only at the highest dose) were administered 0, 512, 620, 750 or 908 mg/kg bw of the test substance via the oral route. The animals were observed for 14 days after dosing and then sacrificed and subjected to gross pathological examination. There was no mortality in the 512 mg/kg bw group while 3 out of 10 and 7 out of 10 rats died in the 620 and 750 mg/kg bw groups, respectively. All 5 animals in the highest dose group (908 mg/kg bw) died. Under the study conditions, the acute oral LD_{50} of the test substance in Sprague-Dawley rats was determined to be 684 mg/kg bw (i.e., equivalent to 226 mg a.i./kg bw) (ECHA) [Kl. score =1].

Inhalation

No acute inhalation data were found for DQAC.

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed using New Zealand White rabbits. Under the conditions of the test, the acute dermal LD_{50} for male and female albino rabbits were determined to be 1,300 mg/kg bw (i.e., equivalent to 429 mg a.i./kg bw) and 1,900 mg/kg bw (i.e., equivalent to 627 mg a.i./kg bw) respectively, and the combined dermal LD_{50} was determined to be 1,600 mg/kg bw (i.e., equivalent to 528 mg a.i./kg bw) (ECHA) [Kl Score=1].

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of a surrogate quaternary ammonium substance, Coco TMAC (active ingredient 33%), using New Zealand White rabbits. Six animals were treated with 0.5 mL undiluted test substance (33%) in a semi-occlusive patch (1" X 1" gauze) that was overwrapped with a gauze binder and secured with dermiform tape. Plastic restraint collars were applied and remained on the animals for the duration of the 4-hour exposure period, after which the tape and test substance were removed. The Draize classification scoring criteria were used to evaluate the irritation potential. Application sites were observed for erythema and oedema at 4, 24, 48 and 72 hours after exposure and then daily up to 14 days. The test substance induced moderate erythema and moderate to severe oedema on all sites.

Remission of irritation signs occurred as the study progressed; however, moderate irritation was still present in one rabbit after study Day 12 (erythema: 2 'slight'; edema: 1 'barely perceptible'). In addition, desquamation was noted on all sites late in the study period and fissuring was present on two sites. The Primary Irritation Index was calculated to be 5.6 (indicative of moderate irritation). Under the study conditions, due to persistence of irritation reactions in one animal as well as desquamation on all sites and fissuring on two sites, the test substance is considered to be severely irritating to skin (ECHA) [Kl. score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using a surrogate substance, quaternary ammonium salt. Nine New Zealand White rabbits received 0.1 mL of undiluted solution in one eye. The other eye remained untreated. The eyelids were held closed for approximately 1 second after instillation. The eyes of three rabbits were washed for approximately 1 minute with 120 mL of lukewarm tap water commencing approximately 30 seconds after dosing. Both eyes were examined for ocular irritation in accordance with the method of Draize approximately 1, 24, 48 and 72 hours after dosing and at 96 hours and 7, 14 and 21 days. In addition, both eyes of all rabbits were further examined at 72 hours and 7, 14 and 21 days with sodium fluorescein and ultraviolet light. Body weights were obtained and recorded on study Day 0 (initiation) and at termination (Day 21). Based on the data obtained, the Maximum Average Scores (according to Kay and Calandra scoring system) for the test substance were calculated to be 96.8 (extremely irritating) at 14 days for the unwashed group and 69.7 (severely irritating) at both 72 and 96 hours for the washed group. Purulent discharge, clear discharge, petite haemorrhage, blanching, corneal epithelial damage and peeling, corneal neovascularisation, sodium fluorescein stain retention, and vascularised granulation scar tissue were observed in all 6 animals. Same effects were observed in the washed group, except for vascularised granulation scar tissue. There were no deaths or remarkable body weight changes during the study period. Under the study conditions, the test substance is considered to cause irreversible effects on the eye (ECHA) [Kl. score = 1].

D. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) study (i.e., Buehler test) was performed on Dunkin-Hartley guinea pigs.

The study was conducted to determine the sensitising potential of a read across substance, C12 -14 trimethyl ammonium chloride (TMAC). A pre-test was conducted to determine non-irritating concentrations to be used in the main study. For the main study the induction was carried out at: topical 0.1% w/v in aqueous ethanol for 6 hours, repeated after 7 and 14 days. Challenge was done two weeks after the last induction treatment (Day 28): control and test animals received 0.1% w/v in acetone for 6 hours on previously untreated site under closed patches. After 18 hours the sites were treated with depilatory cream, rinsed and dried. After 3 hours, challenge sites were evaluated for erythema on a scale of 0-3. Evaluation was repeated 24 hours later. Results of the first grading were: 0/20 (3/20 showed a grade of 0.5; in control 2/10 showed a grade 0.5). Second grading: 0/20 (no erythema was observed in any of the animals); test substance was considered to be non-sensitising (ECHA) [Kl. score = 1].

E. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity Study in Rodents) was performed using Sprague Dawley rats. The 90-day study was conducted to determine the oral repeated dose toxicity of the test substance, Coco TMAC. Sprague-Dawley rats were administered the test substance at concentrations of 0, 100, 500 or 2,000 ppm (i.e., corresponding to 0, 22, 113 and 273 mg/kg bw/day in males and 0, 25, 121, 297 mg/kg bw/day in females) in the diet for 90 days. The active ingredient dose equivalent was calculated to be 0, 7.9, 40.3 and 96.9 mg a.i./kg bw/day in males and 8.8, 42.9, 105.3 mg

a.i./kg bw/day in females. The highest dose of 2,000 ppm was reduced to 1,000 ppm from Day 29 onwards due to deterioration in health of the test animals at 2,000 ppm. At the highest dose, the treatment-related findings were clinical signs of toxicity, reduced body weight gain and food efficiency, organ weight changes and microscopic changes in the spleen and kidneys. At the mid dose, reduced body weight gain (males) and reduced food consumption, reduced absolute heart weight and higher incidence of haemosiderin accumulation in the kidneys of males was observed. No treatment-related effects were observed at the lowest dose. Based on the results of the study, dietary administration of the test substance to rats for a period of 90 days at levels up to 273 mg/kg bw/day resulted in toxicologically significant effects at the high dose and marginal effects at the next lower dose of 113 mg/kg bw/day (500 ppm). No such effects were demonstrated at the lowest dose of 22 mg/kg bw/day (100 ppm). The changes observed at the mid dose (500 ppm) were considered to be minor, isolated effects associated with the reduced palatability of the test substance and were considered not to represent an adverse health effect. Therefore, based on effects on body weight, food efficiency and clinical signs the study authors established the NOAEL at the mid dose level of 500 ppm (i.e., equivalent to 40.3 mg ai./kg bw/day) (ECHA) [Kl. Score = 1].

Inhalation

No data were available.

Dermal

An OECD Guideline 410 (Repeated Dose Dermal Toxicity: 21/28-Day Study) was performed on New Zealand White rabbits. The 28-day study was conducted to determine the repeated dose dermal toxicity of the read across substance, C16 TMAC, in New Zealand albino rabbits (both sexes).

The purity was not specified, and the study included a lower than recommended number of animals (i.e., 10/group rather than 20/group as per the guideline) and histopathology was performed only on limited organs. The test substance (0 and 10 mg test substance/kg bw/day) was applied to the shaved, intact skin of groups of five New Zealand albino rabbits/sex/group for 6.5 to 7 hours, 5 days/week for 4 weeks.

Dermal irritation readings were recorded daily. The animals were weighed weekly during the exposure period. Blood was collected for haematology measurements before initiation of dosing and prior to termination. Liver and kidneys weights were recorded at necropsy and limited histopathology was conducted. There were no systemic treatment-related effects on body weights, haematology, organ weights, gross necropsy findings or histopathology. Treated areas of the skin showed mild to marked acanthosis with active mitosis, hyperkeratosis, and partial to extensive necrosis of the epidermis and hair follicles, partly with encrustation and exudate. Based on the results of the read across study, the NOAEL for systemic effects of DQAC (by read across to Coco TMAC) can therefore be considered to be at 10 mg/kg bw/day (ECHA) [Kl Score = 2].

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on DQAC based on read-across from aluminium compounds are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on DQAC[1]

Test System[1]	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) (Bacterial Reverse Mutation Assay)	-	[1]	2	ECHA

*+, positive; -, negative
1 – based on read across to Coco TMAC.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed. The study was conducted to determine the clastogenic potential of a surrogate test substance, Coco TMAC (active ingredient 33%). Based on the results of a dose range finding assay, a dosage of 468 mg/kg bw (in1% methyl cellulose) was administered by oral gavage to male and female mice. Following dosing, the animals were examined regularly for any clinical signs of reaction.

Bone morrow smears were obtained at three sampling times: 24, 48 or 72 hours after dosing. One smear from each animal was examined for the presence of micronuclei in 1,000 polychromatic erythrocytes. The ratio of polychromatic to normochromatic erythrocytes was assessed by examination of at least 1,000 erythrocytes from each animal. A vehicle control (1% methylcellulose) and a positive control with mitomycin C by intraperitoneal injection were included. At all sampling times, mice treated with the test substance showed no significant increase in the frequency of micronucleated polychromatic erythrocytes. There was no significant decrease in the ratio of polychromatic to normochromatic erythrocytes at any of the three kill times after treatment. The positive control compound, mitomycin C, produced large, highly significant increases in the frequency of micronucleated polychromatic erythrocytes together with large decreases in the ratio of polychromatic to normochromatic erythrocytes and increases in the frequency of micronucleated normochromatic erythrocytes. Under the conditions of the study, the test substance, and by association DQAC, was found to show no evidence of clastogenic potential in the bone marrow cells of mice (ECHA) [Kl. score = 1].

G. Carcinogenicity

Oral

No substance specific data exist.

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

Oral

See discussion on developmental toxicity below.

I. Developmental Toxicity

Dermal

There are no oral developmental toxicity studies of DQAC. However, there is a dermal developmental toxicity study (OECD Guideline 414 - Prenatal Developmental Toxicity Study) of QAS category using C16 TMAC as a surrogate.

The study was conducted in New Zealand White rabbits. Twenty mated female rabbits per group were exposed topically (daily for 2 hours) from Days 7 to 18 of gestation at concentrations of 0, 0.5, 1.0, or 2.0% (equivalent to 0, 10, 20 and 40 mg a.i./kg bw/day, respectively). The control group was treated with deionised water only. Clinical condition and reactions to treatment were recorded at least once daily. Body weights were recorded on Days 0, 3, 6, 9, 12, 15, 18, 21, 24, 27 and 29 of gestation. All surviving females were sacrificed on Day 29 of gestation and the foetuses were removed by caesarean section. At necropsy the females were examined macroscopically. Live foetuses were weighed, sexed and were examined for visceral and skeletal abnormalities. Two control animals, one intermediate and one high dose died during the study. Two of the rabbits that died were aborted prior to death (one control and one intermediate dose). Two additional abortions occurred, one each in the intermediate and high dose groups. Deaths or abortions were not considered to be related to the test substance.

No treatment-related maternal body weight or food intake effects were noted. The incidence of foetal malformations, as well as genetic and developmental variations in the treated groups, was comparable to that of the control group. No other treatment-related effects were noted. Under the study conditions, the NOAEL of DQAC for maternal as well as developmental toxicity is considered to be 40 mg/kg bw/d in rabbits [Kl. score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for DQAC follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The repeated dose NOAEL for DQAC has been determined to be 40.3 mg a.i./kg bw/day. Thus, the NOAEL of 40.3 mg/kgday will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 50/(10 x 10 x 1 x 1 x 1) = 40.3/100 = 0.4 mg/kgday.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (0.4 x 70 x 0.1)/2 = 1.4 mg/L

B. Cancer

No data on carcinogenicity was available. Therefore, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

DQAC does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

DQAC in acute aquatic toxicity studies is very toxic and in chronic aquatic toxicity studies is very toxic with long lasting effects.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on DQAC.

Table 3: Acute Aquatic Toxicity Studies on DQAC[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Salmo gairdneri	96-hour LC_{50}	3.2	2	ECHA
Daphnia magna	48-hour EC_{50}	0.09	2	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	0.062	2	ECHA

1 – data abstracted from quaternary ammonium compounds, Coco TMAC

Chronic Studies

Fish:

A study was conducted to determine the long-term toxicity to Fathead minnow (Pimephales promelas) of the read-across substance, C12-16 ADBAC (purity: 30%). Mortality, hatchability and growth were evaluated. Fish eggs (80 per concentration) were exposed for 34 days to mean measured concentrations of 0, 32.3, 75.9, 134.2, 186.8, 273.2 and 488.7 mg a.i./L of the radiolabelled test substance. Analytical determination was performed and the sample concentrations were verified by liquid scintillation counting. After 7 days, surviving fry from two replicates were thinned to 10 animals per replicate for each exposure group (total of 20 animals per concentration) and exposed to the same concentrations for a 28-day post-hatch static renewal toxicity test. Observations of symptoms and mortality were conducted daily. Under the conditions of the study, the 34-day NOEC for hatchability was 0.274 mg/L, the 34-day NOEC and LC_{50} for survival were 0.032 and 0.094 mg a.i./L, respectively, and the 34-day NOEC for growth was > 0.032 mg/L. Based on the results of the read across study, the 34-day NOEC of 0.032 mg/L is considered relevant for DQAC (ECHA) [KI Score = 2).

Invertebrates:

A study was conducted to determine the long-term toxicity to aquatic invertebrates of the read across substance, C16-18 and C18-unsaturated TMAC as a suitable surrogate for DQAC according to OECD Guideline 211.

Daphnia magna were exposed to six concentrations of the test substance in a 21-day static-daily renewal test in three different water types (i.e., laboratory blended water, well water and river water).

Analytical determination of the test substance was performed. Measured concentrations (µg/L; values represent the geometric mean of the 0- and 24-hour concentration analyses) were southwest well water at 1.6, 3.1, 6.8, 14.6, 30.6 and 60.8 µg a.i./L and river water at 35.7, 53.4, 68.3, 99.1, 122.3 and 309.3 µg a.i./L. The test in blended water was discontinued after 14 days due to inadequate reproduction by control organisms.

Mortality was monitored daily and the number of young produced in each beaker was recorded. Test substance concentrations were verified by analysis and represent the geometric mean of the 0 and 24-hour concentration. Under the test conditions, the 21-day NOEC of the test substance to *Daphnia magna* was equivalent to 0.0068 mg/L and 0.099 mg/L in southwest well and river water, respectively. The NOEC for DQAC was considered equal to 0.0068 mg/L (ECHA) [KI Score = 2].

C. Terrestrial Toxicity

No data were available.

D. Calculation of PNEC

The PNEC calculations for DQAC follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. The lowest acute EC_{50} value was 0.062 mg/L for algae. Results from chronic toxicity studies are available for invertebrates (0.0068 mg/L) and fish (0.032 mg/L). On the basis that the data consists of short-term studies for three trophic levels and long-term results for two trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC value of 0.0068 mg/L. Therefore, the $PNEC_{water}$ is 0.00068 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the substance is expected to substantially disassociate to partition to sediments. Nonetheless, a $PNEC_{sed}$ was calculated using the equilibrium partitioning methodology. The $PNEC_{sed}$ is 31.6 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed}\text{-water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (5.95 \times 10^4/1280) \times 1000 \times 0.00068$
$= 31.6$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$PNEC_{water}$ = 0.00068 mg/L
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 1.2 \times 10^5/1000 \times 1,280]$
$= 5.95 \times 10^4$ m^3/m^3

And:

Kp_{sed} = solid-water partition coefficient (L/kg)
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= 3.1 \times 10^6 \times 0.04$
$= 1.2 \times 10^5$ L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} was calculated as the midpoint of modelled K_{oc} range and determined to be 3.1×10^6 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 28.1 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (6x10^4/1500) \times 1000 \times 0.00068$
$= 28.1$ mg/kg

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$PNEC_{water}$ = 0.00068 mg/L

And:
$Kp_{soil} = K_{oc} \times f_{oc}$
$= 3.1x10^6 \times 0.02$
$= 6.2x10^4$ m^3/m^3

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} was calculated as the midpoint of modelled K_{oc} range and determined to be $3.1x10^6$ L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

DQAC is an organic substance that has been determined to be readily biodegradable. Thus, it does not meet the screening criteria for persistence.

The estimated log K_{ow} is equal to 2.39. Based on the log K_{ow}, DQAC will not have a tendency to bioaccumulate (ECETOC, 2000). Therefore, DQAC does not meet the screening criterion for bioaccumulation.

The chronic toxicity data on DQAC shows a NOEC of <0.1 mg/L. Thus, DQAC meets the screening criteria for toxicity.

However, based on PBT assessment guidance cited above, the overall conclusions for DQAC is that it is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute toxicity - oral

Acute Tox. 3 H301: Toxic if swallowed.

Acute toxicity - dermal

Acute Tox. H311: Toxic in contact with skin.

Skin corrosion / irritation Skin Corr. 1C H314: Causes severe skin burns and eye damage.

Serious eye damage / eye irritation

B. Eye Damage 1 H318: Causes serious eye damage.

C. Labelling

Danger

D. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for DQAC.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be an effective type of air-purifying respirator: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking, and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

DQAC is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). Persistent organic pollutants. Response to UNEC/INC/ CEG-1. Annex 1, Document No. 41. Brussels, Belgium.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

DIETHYLENE GLYCOL

This dossier on diethylene glycol presents the most critical studies pertinent to the risk assessment of diethylene glycol in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-(2-hydroxyethoxy)ethan-1-ol

CAS RN: 111-46-6

Molecular formula: $C_4H_{10}O_3$ or $(CH_2CH_2OH)_2O$

Molecular weight: 106.12 g/mol

Synonyms: Diethylene glycol; 2,2'-oxydiethanol; diglycol; bis(2-hydroxyethyl) ether; 2-hydroxyethyl ether; 2,2'-oxybisethanol; 2-(2-hydroxyethoxy)ethanol; ethanol, 2,2'-oxybis-; 2-(2-hydroxyethoxy)ethan-1-ol; glycol ethyl ether; ethylene diglycol

SMILES: C(COCCO)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Diethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	A colourless viscous liquid	2	ECHA
Melting point	-6.5°C @ 101.3 kPa	2	ECHA
Boiling point	244.9°C @ 101.3 kPa	2	ECHA
Density	1,118 kg/m^3 @ 20°C	2	ECHA
Vapour pressure	0.008 hPa @ 25°C	2	ECHA
Partition coefficient (log K_{ow})	-1.98 (calculated)	2	ECHA
Water solubility	1,000 g/L @ 20°C	2	ECHA
Flash point	138°C	2	ECHA
Auto flammability	372°C	2	ECHA
Viscosity	30 mPa s (dynamic) @ 25°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

The substance is readily biodegradable, is unlikely to bioaccumulate, nor is it likely to adsorb or desorb to soil or sediment to a great extent.

B. Biodegradation

Diethylene glycol is readily biodegradable. In an OECD 301B test, there was 70-80% and 90-100% degradation after 28 days, as determined by CO_2 evolution and DOC removal respectively (ECHA) [KI score = 2].

In an OECD 301A test, there was 90-100% degradation after 28 days, although the 10-day window was missed (ECHA) [KI score = 1]. In a modified MITI I test (OECD 301C), there was up to 92% degradation after 28 days (ECHA) [KI score = 2].

C. Environmental Distribution

No experimental data are available for diethylene glycol. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} value from the molecular connectivity index (MCI) and log K_{oc} are 1 and -0.08 L/kg, respectively (ECHA) [KI Score = 2]. Based on these K_{oc} values, if released to soil, diethylene glycol is expected to not adsorb to soil and have a very high mobility. If released to water, based on the K_{oc} value and its water solubility, it is also not expected to adsorb to suspended solids and sediment.

D. Bioaccumulation

The calculated log K_{ow} for diethylene glycol is -1.98 (Verschueren, 1983). Diethylene glycol has low potential to bioaccumulate. In a 3-day bioaccumulation fish study with Leuciscus idus melanotus, the BCF was determined to be 100 (Freitag et al., 1985) [KI score = 2].

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The substance exhibits low oral acute toxicity. It is not a significant skin or eye irritant, nor is it considered to be a skin sensitiser. No dermal or inhalation repeat dose studies were available but oral repeat does studies suggest moderate urinary dysfunction with oxalate formation in rats. The substance is not genotoxic, carcinogenic nor developmentally toxic.

B. Acute Toxicity

The oral LD_{50} in rats is 19,600 mg/kg (Lenk et al., 1989; ECHA) [KI score = 2]; and 16,500 mg/kg (Laug et al., 1939; ECHA) [KI score = 2].

No deaths were reported in rats exposed to a saturated vapour for 6 hours (OECD, 2007) [KI score = 2]. No deaths were also reported in male and female Aplk:APfSD (Wistar-derived) rats exposed to 5,080 mg/m^3 diethylene glycol aerosol (MMAD = 2.83 µm, GSD = 2.05) for 4 hours (OECD, 2007) [KI score = 2].

The dermal LD_{50} in rabbits was reported to be 12,500 mg/kg (OECD, 2007) [KI score = 2]. The dermal LD_{50} in rabbits was reported to be 13,300 mg/kg (ECHA) [KI score = 4].

C. Irritation

When applied to the skin of rabbits for 24 hours under occlusive conditions, diethylene glycol was essentially non-irritating with a PII score of 0.04 (Guillot et al., 1982, ECHA) [KI score = 2]. In a human repeated irritation patch test, diethylene glycol was minimally irritating to the skin (OECD, 2007) [KI score = 2].

Diethylene glycol was not considered a skin irritant in an *in vitro* reconstructed human epidermis test (ECHA) [KI score = 1].

Instillation of 0.1 mL diethylene glycol into the eyes of rabbits produced minor, transient irritation; no corneal lesions were observed (OECD, 2007) [KI score = 2]. When instilled into the eyes of rabbits, the ocular irritancy was 11.67 based on a modified Kay Calandra scale of 0 to 110 (Guillot et al., 1982, ECHA) [KI score = 2].

D. Sensitisation

Diethylene glycol was not a skin sensitiser to guinea pigs in a maximisation test (OECD, 2007; ECHA) [KI score = 1]. Diethylene glycol was not a skin sensitiser in a human repeat irritation patch test (OECD, 2007; ECHA) [KI score = 4].

E. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their diet 0, 0.085, 0.17, 0.4 and 2.0% diethylene glycol for 225 days. The corresponding average daily intakes were 0, 51, 105, 234 and 1,194 mg/kg/day for males; and 0, 64, 126, 292 and 1462 mg/kg/day for females. In the 0.4% and 2% groups, there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The only finding in the 0.17% group was a 13.2% increase in urinary oxalate excretion in males; no effects were observed in the 0.085% group. The NOAEL and NOEL for this study is considered to be 0.17% (approximately 105 mg/kg/day) and 0.085% (approximately 51 mg/kg/day), respectively (ECHA) [KI score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on diethylene glycol are shown in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Diethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	OECD (2007), ECHA
Bacterial reverse mutation (S. typhimurium strains)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	2	OECD (2007), ECHA
Sister chromatid exchange (CHO cells)	-	-	2	OECD (2007), ECHA

*+, positive; -, negative

In Vivo Studies

Micronuclei were not increased in the bone marrow of NMRI mice given a single intraperitoneal injection of 0, 500, 1,000 or 2,000 mg/kg diethylene glycol (ECHA) [KI score = 1].

G. Carcinogenicity

Oral

Male and female F344 rats were given in their drinking water 0, 1.25 or 2.5% diethylene glycol (97% purity) for two years. The daily intake was estimated to be 0, 1,210 and 2,630 mg/kg/day for males; and 0, 1,160 and 2,550 mg/kg/day for females. Mortality was increased in the 2.5% males; drinking water consumption was increased in the 2.5% males and females. There were no significant differences in the incidence of tumours between treated and control animals (Hiasa et al., 1990; ECHA) [KI score = 2].

Male Osborne-Mendel rats were given in their feed 0, 1, 2 or 4% diethylene glycol for two years. During the first 26 weeks of the study, weight gain was significantly reduced at all dose levels. After the first year, the growth of rats fed the 4% diets was significantly reduced relative to the controls. There were no significant differences in food consumption at any treatment level. Mortality in rats fed the 4% diet was significantly higher than the control group; all animals were found dead before the end of the study (most dying during the last 12 months), compared with 7/12 control deaths. The incidence of bladder stones and bladder tumours increased with diethylene glycol exposure, with 0, 0, 6 and 5 bladder tumours observed in the control, 1, 2 and 4% DEG groups, respectively. Bladder stones were observed in 0, 2, 7 and 11 rats in the control, 1, 2 and 4% groups, respectively. In all but one case, bladder stones were present when bladder tumours were observed, suggesting that chronic irritation was a factor in the production of bladder tumours. The severity and incidence of signs of kidney damage (hydronephrosis, hydroureter, focal tubular atrophy, hyalin cast formation, glomerular atrophy) increased in a treatment-related manner, with gross kidney lesions observed in 1/12, 3/12 and 8/12 of the rats in the low-, mid- and high-dose groups, respectively. Liver damage observed histologically also increased with the level of diethylene glycol exposure. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Fitzhugh and Nelson, 1946) [KI score = 3].

Male and female rats were given in their feed 0, 2 or 4% diethylene glycol (containing 0.031% ethylene glycol) for two years. Rats were either just weaned, 2 months old or 12 months old at the initiation of the exposure. The dietary concentration of diethylene glycol was adjusted for the food consumption and body weight of each group. For 4% diet, the dosage in weanlings was 5,400 mg/kg/day for the first 28 days, approximately 3,700 mg/kg/day during the next two-week period, gradually declined to about 2,000 mg/kg/day over the next three months and remained at that level for the rest of the study. A study average of 2,300 mg/kg/day for weanlings fed 4% in the diet was calculated from data provided by the authors. None of the 12-month old male rats included in the study survived, whereas all the females in that group survived to termination of the study. Although weanling rats developed more bladder stones than the other groups, the difference was insignificant. The yearling rats developed their bladder stones somewhat earlier. The yearling rats in the 4% groups had the highest stone formation (8 out of 20 rats) and had the only bladder tumour in this dose group; the rat with the bladder tumour also had bladder stones. No bladder stones or tumours were observed in rats of any age in the control or in the 2% groups. The bladder tumours associated with the stones were considered to be the result of mechanical irritation, and diethylene glycol was not considered to be a primary rat carcinogen. The LOAEL and NOAEL for this study were dietary concentrations of 4% and 2% (approximately 2,300 and 1,200 mg/kg), respectively. It cannot be ruled out that this older study, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity (Weil et al., 1965) [Kl score = 3].

H. Reproductive Toxicity

In a two-generation study, male and female rats were dosed by oral gavage with 1 mL/100 g body weight of a 20% aqueous solution of diethylene glycol (approximately 2 mL/kg/day) for 8 weeks. A control group was given daily oral gavage doses of 1 mL/100 g body weight distilled water. Five of the treated females were dosed with diethylene glycol until parturition, the other five until the pups were weaned. Treatment of the P-generation with diethylene glycol for 12 weeks did not impair reproduction. The test animals and the controls became pregnant at almost the same time, litter size averaged 8-10 young, and the young exhibited similar, uniform development. Growth and onset of oestrus were not affected by treatment. The endocrine glands investigated showed no differences from the controls with regard to weight and fine structure. The receptiveness and litter size of the untreated F1 generation were the same as those of the P-generation, and the F2 generation was normal with regard to weight gain, onset of sexual maturity and weight as well as histology of the organs examined. The NOAEL for this study was calculated to be 2,200 mg/kg/day (Wegener, 1953; ECHA) [Kl score = 2].

A continuous breeding protocol (RACB) was used to study the reproductive toxicity of diethylene glycol in mice. Male and female CD-1 mice were administered in their drinking water 0, 0.35, 1.75 or 3.5% diethylene glycol. Mice were exposed for 7 days prior to mating, 98 days during cohabitation of breeding pairs and a further 23 days after segregation of each pair.

Breeding study: The mice given 1.75% or 3.5% diethylene glycol consumed significantly more drinking water than did the controls. On the basis of water consumption and body weight data, the 0, 0.35, 1.75 and 3.5% dose groups were equivalent to average daily intakes of 0, 612, 3,062 or 6,125 mg/kg/day, respectively. There was no treatment-related mortality. In the 3.5% dose group, there was significant decreases in the number of litters produced per pair, number of live pups per litter, proportion of pups born alive, and the absolute and adjusted pup weights. A significant dose-related trend for reduced absolute pup weights was also observed. Exposure to the 3.55 dose group also resulted in a significant increase in the cumulative days to litter and fewer breeding pairs were able

to produce litters: 82%, 76%, and 59% of the pairs exposed to 3.5% in the diet produced the third, fourth or fifth litters, respectively, whereas 97-100% of the control group produced litters.

Crossover mating: The mating index and the fertility of the 3.5% dosed males or females were unaffected compared with the control mice. However, live pup weight was decreased in the highest-dose group, in which a 9% difference was observed for the offspring of the control males and the treated females. At the end of this test the parental animals (F0 of breeding study) were necropsied. For the male mice there were no significant differences in the body or organ weights, either absolute or adjusted for body weight. Analysis of the cauda epididymal contents of F0 males at necropsy indicated that there were no effects of diethylene glycol in the highest-doses group on the sperm concentration or the percentage of motile or abnormal sperm. The mean body weight of the 3.5% dosed F0 females was significantly decreased relative to the control females. The magnitude of this decrease was approximately 7%. These animals also exhibited significantly decreased absolute liver and pituitary weights, but their organ-to body weight ratios were not different from controls. There were no significant treatment-related gross or histopathological lesions in the organs examined from the male and female F0 mice (Williams et al., 1990) [Kl score = 2].

I. Developmental Toxicity

Time-pregnant CD rats were dosed by oral gavage with 0, 1,118, 4,472 or 8,944 mg/kg on gestational days 6-15. In the high-dose females, there were reduced body weight gain, reduced food consumption, increased water consumption, increased liver and kidney weights and histopathological changes in the kidney. The mid-dose females exhibited only increased water consumption. There were no treatment-related effects on corpora lutea or implantations. Foetal body weights were reduced in the high-dose animals. Total or individual external or visceral variations were similar between treated and control groups; however, individual skeletal variations were significantly increased in the mid- and high- dose groups. The pattern of delayed ossification was considered consistent with reduced foetal body weight. Malformations were similar between treated and control groups. The maternal and developmental NOELs for this study were considered to be 1,118 mg/kg/day (Ballantyne and Snellings, 2005) [Kl score = 2].

Time-pregnant CD-1 mice were dosed by oral gavage with 0, 559, 2,795 or 11,180 mg/kg/day during gestational days 6-15. In the high-dose females, there was mortality, clinical signs, and increased water consumption; only increased water consumption was observed in the mid-dose females. Foetal body weights were significantly reduced in the high-dose animals. There were no increases in variations or malformations between treated and control animals. The maternal and developmental NOELs were 559 and 2,795 mg/kg/day, respectively (Ballantyne and Snellings, 2005) [Kl score = 2].

Groups of 15 pregnant Himalayan rabbits were administered oral (gavage) doses of 0, 100, 400 or 1,000 mg/kg DEG on gestational days 7-19. No maternal toxicity was observed at any of the DEG doses administered. The foetal and litter incidence of skeletal, soft tissue and external anomalies or variations were comparable to those of the control and/or historical control groups. The authors set the maternal and developmental toxicity NOEL at greater than 1,000 mg/kg (Hellwig et al., 1995) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The lowest NOAEL reported in the repeat dose toxicity study is 105 mg/kg/day based on the 225-day rat dietary study. Although, there was a 13.2% increase in oxalate excretion at this dose level, this was considered a biomarker and not an indicator of toxicity. At 0.4% (the LOAEL), there were oxalate crystalluria and mild defects of renal function (increased urine volume), as measured by concentration tests. The NOAEL of 105 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x U_{FD})

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 105/(10 x 10 x 1 x 1 x 1) = 105/100 = 1.0 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (1.05 x 70 x 0.1)/2 = 3.7 mg/L

B. Cancer

A two-year study of in rats showed no carcinogenic effects when diethylene glycol was administered in drinking water (Hiasa et al., 1990). In older studies, bladder tumours were observed in rats given diethylene glycol in feed; the tumours are considered to be the result of physical irritation from the bladder stones that also were noted in the same animals (Fitzhugh and Nelson, 1946; Weil et al., 1965). It cannot be ruled out that these older studies, which showed a significant increase in bladder stones and bladder tumours, may have been influenced by the presence of ethylene glycol as an impurity. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The substance is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on diethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Diethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	75,200	2	ECHA
Oncorhynchus mykiss	96-hour LC_{5}	66,000	2	ECHA
Daphnia magna	24-hour EC_{50}	>10,000	2	ECHA
Daphnia magna	48-hour EC_{50}	65,980	2	ECHA
Daphnia magna	48-hour EC_{50}	62,630	2	ECHA

Chronic Studies

In ECHA, the aquatic toxicity of the 'ethylene glycol and higher glycols' (mono-, di-, tri-, tetra- and pentaethylene glycol) is evaluated in a read-across approach. Data on all three trophic levels (fish, *daphnia*, algae) are available to describe the aquatic toxicity of the glycol read-across members. Due to the fact, that not for each single substance data for all required endpoints are available, a weight of evidence approach is used, which includes additional information based on QSAR calculation with the EpiWin-Program ECOSAR v1.11. Measured data, as well as estimated data, demonstrate that all glycols within the read-across are not harmful to aquatic organisms. No adverse effects on aquatic organisms occurred up to concentrations above 100 mg/L (ECHA).

No data for fish was available for diethylene glycol. However, chronic studies for fish are available for ethylene glycol (CAS No.: 107-21-1). The 7-day NOEC for the fathead minnow (*Pimephales promelas*) was determined to be 15,380 mg/L based on the weight of the test organisms (ECHA) [Kl Score = 2].

No data for invertebrates was available for diethylene glycol. However, three studies were conducted with Dapnids (*Ceriodaphnia dubia* or *Daphnia magna*) for ethylene glycol (CAS-No.: 107-21-1) or triethylene glycol (CAS No.: 112-27-6). The study with ethylene glycol was conducted according to USEPA guideline 600/4-89/001 with *Ceriodaphnia dubia* as test species. The 7-day NOEC for reproduction was determined to be 8,590 mg/L ethylene glycol (nominal). Two studies

measured the effect of triethylene glycol on the reproduction of *Daphnia magna*. One study was conducted according to the national standard ASTM (E 47.01, Draft No. 1, "Draft proposed standard practice for conducting renewal life cycle toxicity tests with Daphnia magna"). In this test the Daphnids were exposed to triethylene glycol for 21 days. Based on reproduction the reported NOEC is > 15,000 mg/L triethylene glycol (nominal) (ECHA) [KI Score = 2].

Data for algae was available for diethylene glycol. The 8-day TGK to algae *Scenedesmus quadricauda* was determined to be 2,700 mg/L for diethylene glycol (ECHA) [KI score = 2].

From the QSAR calculations it can be expected for diethylene glycol that algae are slightly more sensitive (ChV = 1,200 mg/L) than invertebrates (ChV = 1,891 mg/L) or fishes (ChV = 7,694 mg/L) (ECHA) [KI Score = 2].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for diethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C50 values are available for fish (66,000 mg/L), and Daphnia (> 10,000 mg/L). Results from a chronic algae study is available on diethylene glycol (2,700 mg/L). On the basis that the data consists of short-term results from two trophic levels and a long-term result from one trophic level, an assessment factor of 100 has been applied to the lowest reported value, which is the chronic value for algae. The $PNEC_{water}$ is 27 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 17.3 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.89/1280) \times 1000 \times 27$
$= 17.3$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.89\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.36 mg/kg soil dry weight.

The calculations are as follows:

$PNECsoil = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 27

= 0.36 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for diethylene glycol based on the molecular connectivity index (MCI) is 1 L/kg (USEPA, 2017).

f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diethylene glycol has been shown to be readily biodegradable; thus, it does not meet the screening criteria for persistence.

The calculated log K_{ow} is -1.98, and the experimental BCF is 100. Thus, diethylene glycol does not meet the screening criteria for bioaccumulation.

The lowest chronic toxicity value for diethylene glycol is > 0.1 mg/L. Thus, diethylene glycol does not meet the criteria for toxicity.

Therefore, diethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELING (ABSTRACTED FROM PUBCHEM)

A. Classification

Irritant

B. Labelling

Danger

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS) (ABSTRACTED FROM PUBCHEM)

A. First Aid

Eye Contact

First check the victim for contact lenses and remove if present. Flush victim's eyes with water or normal saline solution for 20 to 30 minutes while simultaneously calling a hospital or poison control center. Do not put any ointments, oils or medication in the victim's eyes without specific instructions from a physician. IMMEDIATELY transport the victim after flushing eyes to a hospital even if no symptoms (such as redness or irritation) develop.\

Skin Contact

IMMEDIATELY flood affected skin with water while removing and isolating all contaminated clothing. Gently wash all affected skin areas thoroughly with soap and water. If symptoms such as redness or irritation develop, IMMEDIATELY call a physician and be prepared to transport the victim to a hospital for treatment.

Inhalation

IMMEDIATELY leave the contaminated area; take deep breaths of fresh air. If symptoms (such as wheezing, coughing, shortness of breath, or burning in the mouth, throat, or chest) develop, call a physician and be prepared to transport the victim to a hospital. Provide proper respiratory protection to rescuers entering an unknown atmosphere. Whenever possible, Self-Contained Breathing Apparatus (SCBA) should be used; if not available, use a level of protection greater than or equal to that advised under Protective Clothing.

Ingestion

DO NOT INDUCE VOMITING. If the victim is conscious and not convulsing, give 1 or 2 glasses of water to dilute the chemical and IMMEDIATELY call a hospital or poison control center. Be prepared to transport the victim to a hospital if advised by a physician. If the victim is convulsing or unconscious,

do not give anything by mouth, ensure that the victim's airway is open and lay the victim on his/her side with the head lower than the body. DO NOT INDUCE VOMITING. IMMEDIATELY transport the victim to a hospital.

Notes to Physician (abstracted from PubChem)

The patient should be resuscitated with isotonic crystalloidal fluids, and acidosis should be corrected. Early treatment with a competitive ADH inhibitor (e.g., 4-methylpyrazole or ethanol), hemodialysis and supportive care offer the best hope for patient recovery.

Ensure that adequate decontamination has been carried out. If patient is not breathing, start artificial respiration, preferably with a demand-valve resuscitator, bag-valve-mask device or pocket mask, as trained. Perform CPR as necessary. Immediately flush contaminated eyes with gently flowing water. Do not induce vomiting. If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain an open airway and prevent aspiration. Keep patient quiet and maintain normal body temperature.

Basic treatment: Establish a patent airway (oropharyngeal or nasopharyngeal airway, if needed). Suction if necessary. Watch for signs of respiratory insufficiency and assist ventilations if necessary. Administer oxygen by nonrebreather mask at 10 to 15 L/min. Monitor for pulmonary oedema and treat if necessary. Monitor for shock and treat if necessary. Anticipate seizures and treat if necessary. For eye contamination, flush eyes immediately with water. Irrigate each eye continuously with 0.9% saline (NS) during transport. Do not use emetics. For ingestion, rinse mouth and administer 5 mL/kg up to 200 mL of water for dilution if the patient can swallow, has a strong gag reflex and does not drool. Administer activated charcoal.

Advanced treatment: Consider orotracheal or nasotracheal intubation for airway control in the patient who is unconscious, has severe pulmonary oedema or is in severe respiratory distress. Positive-pressure ventilation techniques with a bag-valve-mask device may be beneficial. Consider drug therapy for pulmonary oedema. Monitor cardiac rhythm and treat arrhythmias if necessary. Start IV administration of D5W /SRP: "To keep open", minimal flow rate. Use 0.9% saline (NS) lactated Ringer's (LR) if signs of hypovolemia are present. For hypotension with signs of hypovolemia, administer fluid cautiously. Consider vasopressors if patient is hypotensive with a normal fluid volume. Watch for signs of fluid overload. Treat seizures with diazepam or lorazepam. Use proparacaine hydrochloride to assist eye irrigation.

Medical Conditions Aggravated by Exposure

Respiratory conditions (asthma, etc.)

Emergency Personnel Protection

Wear a self-contained breathing apparatus in pressure-demand, MSHA/NIOSH (approved or equivalent), and full protective gear. During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion. Use water spray to keep fire-exposed containers cool.

B. Fire Fighting Information (abstracted from Comet Chemical SDS 2013)

Extinguishing Media

Use powder, alcohol-resistant foam, water spray, carbon dioxide.

Specific Exposure Hazards

Combustible when exposed to heat or flame; can react with oxidising materials.

Special Protective Equipment for Firefighters

Firefighters must use standard protective equipment including flame retardant coat, helmet with face shield, gloves, rubber boots, and in enclosed spaces, SCBA. Firefighters should wear proper protective equipment and self-contained breathing apparatus with full face piece operated in positive pressure mode. Move containers from fire area if safe to do so. Water spray may be useful in cooling equipment exposed to heat and flame.

C. Accidental Release Measures

Personal Precautions

Restrict access to area until completion of clean-up. Ensure clean-up is conducted by trained personnel only. All persons dealing with clean-up should wear the appropriate protective equipment including self-contained breathing apparatus.

Environmental Precautions

Ventilate the area. Stop spill or leak at source if safely possible. Dike for water control. Contain and absorb spilled liquid with non-combustible, inert absorbent material (e.g., sand), then place absorbent material into a container for later disposal.

Steps to be Taken if Material is Released or Spilled

Absorb spill with inert material (e.g., vermiculite, sand or earth), then place in suitable container. Clean up spills immediately, observing precautions in the Protective Equipment section. Provide ventilation.

D. Storage and Handling

General Handling

Wear protective gloves/clothing and eye/face protection. Use with adequate ventilation. Do not ingest. Do not breathe mist or vapour. Avoid contact with eyes, skin and clothing. Wash with soap and water after handling. Keep away from extreme heat and flame. Keep away from acids and other incompatibles. Keep containers tightly closed when not in use.

Other Handling Precautions

Wash thoroughly after handling. Use with adequate ventilation. Avoid breathing vapours from heated material. Avoid contact with eyes, skin and clothing. Keep container tightly closed. Wash clothing before reuse. Avoid breathing spray or mist.

Storage

Store in a cool, dry, well-ventilated area. Store away from areas of excessive heat, open flames, sparks and other possible sources of ignition. Keep away from incompatibles. Storage area should be

clearly identified, clear of obstruction and accessible only to trained and authorised personnel. Inspect periodically for damage or leaks.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for diethylene glycol.

Engineering Controls

Good general ventilation should be used. Localised ventilation should be used where vapours, mist or aerosols may be generated.

Personal Protection Equipment

Respiratory Protection: Wear an approved respirator with dust/mist pre-filters if any exposure to dust or mist is possible.

Hand Protection: Wear appropriate chemical-resistant gloves.

Skin Protection: Wear protective clothing to minimise skin contact.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Ballantyne, B., and Snellings, W.M. (2005). Developmental toxicity study with diethylene glycol by gavage to CD rats and CD-1 mice. Food Chem. Toxicol. 43: 1637-1646.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fitzhugh, O.G., and Nelson, A. (1946). Comparison of the chronic toxicity of triethylene glycol with that of diethylene glycol. J. Ind. Hyg. Tox. 25: 40-43.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. An experimental method for the assessment of the behavior of organic chemicals in the ecosphere by means of simple laboratory tests with 14C labeled chemicals. Chemosphere 14: 1589-1616.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Sci. 4: 67-80.

Hellwig, J., Klimisch, H.J., and Jäckh, R. (1995). Investigation of the prenatal toxicity of orally administered diethylene glycol in rabbits. Fundam. Appl. Toxicol. 28: 27-33. (1995).

Hiasa, Y., Kitahori, Y., Morimoto, J., Konishi, W., and Ohshima, M. (1990). Absence of carcinogenic or promoting effects of diethylene glycol on renal tumourigenesis in rats. J. Toxicol. Pathol. 3: 97-104.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Laug, E., Calvery, H.O., Morris, H.J., and Woodward, G. (1939). The toxicology of some glycols and derivatives. J. Ind. Hyg. Toxicol. 21: 173-201.

Lenk, W., Löhr, D., and Sonnenbichler, J. (1989). Pharmacokinetics and biotransformation of diethylene glycol and ethylene glycol in the rat. Xenobiotica 19: 961-979.

OECD. (2007). SIDS Dossier on the HPV Chemical Diethylene Glycol (CAS No. 111-46-6).

Pubchem. https://pubchem.ncbi.nlm.nih.gov/compound/DI_Hydroxyethyl_ether#section=InChI Accessed January 2022.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Verschueren, K. (1983). Handbook of Environmental Data on Organic Chemicals, 2nd Edition, Van Nostrand, New York: 1,310

Wegener, H. (1953). The reproductive capacity of rats after the action of diethylene glycol. Arch. Exper. Path. u. Pharmakol. 220: 414-417.

Weil, C.S., Carpenter, C. and Smyth, H.F. (1965). Urinary bladder response to diethylene glycol. Arch. Environ. Health 77: 569-581.

Williams, J., Reel, J., George, J., and Lamb, IV, J. (1990). Reproductive effects of diethylene glycol and diethylene glycol monoethyl ether in Swiss CD-1 mice assessed by a continuous breeding protocol. Fundam. App. Toxicol. 74: 622-635.

DIUTAN (CAS NO. 595585-15-2)
DIUTAN GUM (CAS NO. 125005-87-0)

This dossier on diutan and diutan gum presents the most critical studies pertinent to the risk assessment of these substances in its use in coal seam gas extraction activities. Diutan (CAS No. 595585-15-2) can also be referred to as diutan gum (CAS No. 125005-87-0). This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained for diutan gum from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): (2R,3R,4S,5S)-2,3,4,5-tetrahydroxyhexanal (2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanal (2S,3S,4S,5R)-2,3,4,5-tetrahydroxy-6-oxohexanoic acid acetic acid calcium dihydride hydrate magnesium dihydride potassium hydride sodium hydride

CAS RN: 125005-87-0

Molecular formula: $C_{20}H_{46}CaKMgNaO_{21}$

Molecular weight: Not applicable as substance is a UVCB.

Synonyms: Diutan gum; S 657; S-657 Gum; GEOVIS XT; GEOVIS XTL; KELCO-CRETE DG

Chemical Name (IUPAC): D-glucuronic acid, polymer with 6-deoxy L-mannose and D-glucose, acetate, Ca Mg K Na salt

SMILES: Not applicable

CAS RN: 595585-15-2

Molecular formula: $(C_6H_{12}O_6.\ C_6H_{12}O_5.\ C_6H_{10}O_7)x.C_2H_4O_2.\ xCa.xK.xMg.xNa$

Molecular weight: Not applicable as substance is a UVCB.

Synonyms: Diutan; D-Glucurono-D-gluco-6-deoxy-L-mannan, acetate, calcium magnesium potassium sodium salt.

SMILES: Not applicable

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1:Overview of the Physico-chemical Properties of Diutan Gum (CAS No. 125005-87-0)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Off-white solid powder	1	ECHA
Melting Point	No melting point was determined. Test substance decomposed at >175°C.	2	ECHA

Property	Value	Klimisch score	Reference
Boiling Point	No data	-	-
Density	1430 Kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	~0.1 kPa @ 25°C	-	NICNAS, 2010
Partition Coefficient (log K_{ow})	-3.56 @ 20°C	2	ECHA
Water Solubility	40 g/L @ 20°C	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Diutan/diutan gum is readily biodegradable, is not expected to bioaccumulate, and has a low potential to adsorb to soil.

B. Biodegradation

A GLP-compliant study conducted in accordance with the OECD guideline was available. The test material (diutan gum) attained 95% degradation after 28 days and satisfied the 10-day window validation criterion, whereby 60% degradation must be attained within 10 days of the degradation rate exceeding 10%. The test material can therefore be considered to be readily biodegradable under strict terms and conditions of the OECD guideline 301B [Kl Score = 1] (ECHA).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

No experimental data are available for diutan/diutan gum. Based on the low experimentally determined log K_{ow} (-3.56) value, the substance has a low potential to adsorb to soil and will be highly mobile in soil.

D. Bioaccumulation

No experimental data are available for diutan/diutan gum. Based on the low log K_{ow} (-3.56), the potential for bioaccumulation is low.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Diutan has low acute toxicity by the oral and inhalation routes. It is not irritating to the skin and eyes and is not a skin sensitiser. No systemic effects were seen in repeated dose oral toxicity studies in rodents. The substance is not carcinogenic or genotoxic. No reproductive or developmental toxic effects were identified.

B. Toxicokinetics

A screening level toxicokinetic study was performed using male and female Sprague-Dawley rats. Radio labeled Gellan Gum mixed with corn oil was administered via gavage. Specific activity of formulated dose was checked by sample combustion and scintillation counting.

The study was performed in three stages. Stage 1 involved CO_2 collection from 1 male, 1 female. Stage 2 consisted of faeces collection and tissue distribution analysis from 4 males, 4 females. One female was excluded from the study due to abnormal findings at necropsy suggestive of maldosing. Stage 3 involved collection of blood levels from 4 males, 4 females.

Stage 1 results showed less than 0.55% of dosed radioactivity was expired in the form of $^{14}CO_2$. Stage 2 results indicated that females excreted 1.85 +/- 0.55% of dosed ^{14}C in urine, 86.79 +/- 3.08% in faeces. The Stage 3 results recorded low levels of radioactivity in the blood: mean peak blood radioactivity in both sexes was close to 3,000 DPM/mL blood, occurring around 5.5 hours post-dosing in males, 5.25 hours post-dosing in females.

The low levels of radioactivity recorded in tissues and blood samples and the high levels of radioactivity excretion in faeces suggest very little absorption from the gastrointestinal tract occurred following oral dosing. No potential for bioaccumulation was indicated by the study findings. Based on the close chemical similarity between gellan gum and diutan, it is reasonable to predict that a comparable pattern of non-absorption would be seen if diutan were to be similarly tested (ECHA) [Kl. score = 2].

C. Acute Toxicity

<u>Oral</u>

An acute Limit Test, in accord with USEPA test guideline USEPA 40 CFR 163.81-1 was performed. Six male and six female Sprague Dawley rats were administered 5,000 mg/kg in corn oil via gavage. Rats were weighed prior to dosing, then 7 and 14 days later and were observed 1, 2 and 4 hours post-dose, then daily up to 14 days after dosing. Gross pathology observations were made at necropsy. No evidence of toxicity was seen. A no observed effect level (NOEL) of 5,000 mg/kg was determined (ECHA) [Kl Score = 2].

<u>Inhalation</u>

A standard acute inhalation study was performed according to method USEPA 40 CFR 163.81-3. Five male and five female Sprague-Dawley rats were exposed whole body to substance dust for 4 hours in air at a measured test atmosphere of 0.316 mg/L (mean across sampling times). Particle size distribution (measured using Andersen plate sampler during the final 15 minutes of exposure): 100% < 10 microns, 28.9% ≤ 1.1 microns.

After 14 days post-exposure observation, all rats were terminated. Following gross pathology observations at necropsy, lungs and tracheal structures were collected into buffered formalin. Lungs and tracheal samples were also collected from a sample of rats taken at the time of animal delivery (pre-study) and from a supplementary non-exposed control group (additional to the air-exposed controls) at study termination.

No evidence of toxicity was seen after 4-hour exposure of rats to the test substance in a dust atmosphere (nominally 4.9 mg/L and measured at 0.316 mg/L). The difference between nominal and

measured concentrations may indicate that close to a maximum practicable concentration was achieved (ECHA) [KI Score = 2].

Dermal

No studies were available.

D. Irritation

Skin

A non-guideline dermal irritation study was performed on Dunkin-Hartley guinea pigs. The substance was applied in arachis oil at four different concentrations at separate sites on the clipped flanks: 5, 10, 25, 50%. Application sites were occluded for 24 hours and observed 1, 24 and 48 hours after dressing removal. Erythema and oedema scores at 50% concentration did not indicate test substance was irritating (ECHA) [KI Score = 2].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) was performed on albino rabbits. 100 mg substance was applied to one eye while the contralateral eye served as a control. Ocular reactions were observed at 24, 48 and 72 hours post-treatment. Cornea opacity, iris and conjunctivae scores were not indicative of irritation. Therefore, diutan is considered not irritating (ECHA) [KI Score = 2].

E. Sensitisation

An OECD Guideline 406 (Skin Sensitisation) was performed on male Dunkin-Hartley guinea pigs. Intradermal induction was performed with 5% w/w in dried arachis oil. Topical (epicutaneous) induction was performed with 50% w/w in dried arachis oil. Topical challenge was performed with 25% and 10%, w/w in dried arachis oil. The test material produced a 0% (0/10) sensitisation rate and was determined as a non-sensitiser to guinea pig skin under the conditions of the test (ECHA) [KI score = 1].

F. Repeated Dose Toxicity

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) was performed using the structural analogue K9A50: gellan gum (EC 275-117-5). Male and female Sprague-Dawley rats (20 each) were dosed at 3%, 4.5% and 6% nominally in the diet.

Mortality was checked twice daily; clinical signs were recorded once daily. Bodyweights and food consumption recorded pre-treatment and weekly during treatment. Opthalmoscopy checks (control and high-dose groups) were performed pre-treatment and prior to termination.

Haematology, blood chemistry and urinalysis were checked pre-treatment (health screen satellite group) and (together with faecal moisture content) in weeks 6 and 12 of treatment period (10 or 12 rats/sex/group).

Rats fed 6% gellan gum in diet for 13 weeks (corresponding to daily intakes ranging from 2.95 to 7.26 g/kg/day) showed no evidence of treatment related toxicity. It is reasonable to predict that a similar

pattern of low subchronic toxicity would be seen if diutan were to be tested in the same way (ECHA) [KI score = 2].

Inhalation

No adequate studies for human health risk assessment are available.

Dermal

No adequate studies for human health risk assessment are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on diutan are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Diutan[1]

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-*	-*	2	ECHA

1 – Surrogate substance (Biozon - EC 476-190-8) evaluated
*+, positive; -, negative.

Diutan is not expected to induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation.

In Vivo Studies

An OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test) was performed using the surrogate, Gellan gum (EC 275-117-5). Oral administration of gellan gum at up to 2 x 450 mg/kg produced no detectable increase in the frequency of micronucleated bone marrow cells in treated mice. It is predictable that diutan would give a similarly negative result if tested in the same manner.

H. Carcinogenicity

A mouse carcinogenicity study of the close chemical analogue gellan gum found that inclusion in diet at up to 3% had no significant toxic effect and did not increase the incidence of neoplastic (malignant or benign) or non-neoplastic lesions. The overall mean achieved intake of gellan gum at the highest tested level was calculated to be 4.9 g/kg/day (males) or 6.2 g/kg/day (females).

The open literature also includes a short summary of a rat carcinogenicity study which supports the conclusion that gellan gum is non-carcinogenic. The Joint FAO/WHO Expert Committee on Food Additives(1990) cites a carcinogenicity study in which rats first exposed to gellan gum in utero were then fed gellan gum at up to 5% in the diet for approximately 104 weeks.

No neoplastic or non-neoplastic changes were associated with gellan gum exposure.

The close chemical analogue gellan gum showed no evidence of carcinogenicity in rodent carcinogenicity studies. It is predictable that diutan would give a similarly negative result if tested in the same manner (ECHA) [KI Score = 2].

I. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed. Male and female Sprague Dawley rats were dosed with the diutan surrogate Gellan gum (EC 275-117-5) at 2.5, 3.8 and 5% in the diet per study guidelines.

Details on results (P0): No toxicologically significant effects were noted for general toxicity or reproductive function. No evidence of parental toxicity and no effect on reproductive performance seen at highest treatment level (5%).

Details on results (F1 and F2): No evidence of toxicity, no effect on reproductive performance and no effect on development of F1 rats seen at the highest treatment level (5%). No effects on F2 development seen at the highest treatment level (5%).

Administration of gellan gum to P and F1 rats at levels up to 5% in diet resulted in achieved adult intakes within the range 2.8-6.5 g/kg (males), 3.0-4.2 g/kg (females). No evidence of toxicity or adverse effects on reproductive performance or development was seen. Given the close similarity between gellan gum and diutan, it is reasonable to predict that diutan would show a similar lack of toxicity to reproduction (ECHA) [KI Score = 2].

J. Developmental Toxicity

An OECD Guideline 414 (Prenatal Developmental Toxicity Study) was performed with the diutan surrogate gellan gum (EC 275-117-5). The substance was administered via diet and restricted to the period of organogenesis (gestation dates 6-15). Females mated with one male of proven fertility; mating confirmed by presence of spermatozoa in vaginal lavage (designated gestation day 0).

Maternal Toxicity

No evidence of maternal toxicity was seen. Minor gross pathology findings at termination were considered unrelated to treatment. Pregnancy rate was at least 88% in all groups.

Embryotoxic / Teratogenic effects

The incidence of major malformations in test groups was no different from that among controls. Subcutaneous oedema and accompanying skin changes in 7 foetuses from one litter made the occurrence of minor external/visceral anomalies significantly raised at 3.8%. Cases of reduced ossification at 2.5% (mainly ribs) and 3.8% (mainly parietal bones) made group values significantly different from controls. Common skeletal (sternebrae 1-4) variants were significantly increased at 3.8%. None of the above minor anomalies/variants were seen in rats of the highest treatment group (5% in diet); it was concluded that they were not related to gellan gum exposure. It is reasonable to predict that diutan would show a similar lack of toxicity to development (ECHA) [KI score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for diutan follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

An OECD Guideline 408 (Repeated Dose 90-Day Oral Toxicity in Rodents) was performed using the structural analogue K9A50: gellan gum (EC 275-117-5). The lowest NOAEL of 2.95 g/kg/day (i.e., 2,950 mg/kg bw/day) from this study was used to determine the oral RfD and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 2950/(10 x 10 x 1 x 1 x 1) = 2950/100 = 29.5 mg/kg bw/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (29.5 x 70 x 0.1)/2 = 103.25 mg/L

B. Cancer

The single carcinogenicity study by the oral route indicates diutan is not a carcinogen. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Diutan does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Diutan is of low acute toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 presents the results of acute aquatic toxicity studies on diutan/diutan gum.

Table 3: Acute Aquatic Toxicity Studies on Diutan Gum

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss (Rainbow Trout)	96-hour LC_{50}	100	1	ECHA
Daphnia magna	48-hour LC_{50}	> 100	1	ECHA
*Desmodesmus subspicatus (*previous name*: Scenedesmus subspicatus)*	72-hour EC_{50}	> 100 (growth rate and biomass)	1	ECHA

Chronic Studies

No data is available.

C. Terrestrial Toxicity

No data is available.

D. Calculation of PNEC

PNEC calculations for diutan acid follow the methodology discussed in DEWHA (2009).

PNEC water

Acute experimental results are available for three trophic levels (Table 3). Acute E(L)C50 values are available for fish (100 mg/L), invertebrates (> 100 mg/L) and algae (>100 mg/L). On the basis that the data consists of short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported value. The $PNEC_{water}$ for diutan is 1.0 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the low K_{ow} indicates that diutan is not expected to partition to sediments. Therefore, a the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.63 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
= (0.809/1280) x 1000 x 1.0
= 0.63 mg/kg sediment wet wt.

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
= 0.8 + [(0.2 x 0.035/1000 x 2400]
= 0.82 m^3/m^3

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
= 0.865 x 0.04
= 0.035 L/Kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for calculated from EPI Suite™ using the MCI is 0.865 L/kg .
F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Moreover, diutan is biodegradable and due to its low K_{ow}, is not expected to partition to soil. Therefore, a $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.01 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
= (0.02/1500) x 1000 x 1.0
= 0.01 mg/kg soil dry weight

Where:
Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
= 0.865 x 0.02
= 0.017 m^3/m^3

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for calculated from EPI Suite™ using the MCI is 0.865 L/kg.
F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Diutan/diutan gum is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Bioaccumulation of diutan/diutan gam is not expected to occur based on it log K_{ow} value of -3.56. Thus, diutan/diutan gum does not meet the screening criteria for bioaccumulation.

No chronic toxicity data is available. The E(L)C_{50} values from the acute aquatic toxicity studies on diutan/diutan gum are > 1 mg/L. Thus, diutan/diutan gum does not meet the criteria for toxicity.

Therefore, diutan/diutan gum is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

Not Classified

C. Pictogram

Not Classified

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If eye irritation persists, seek medical attention, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

No significant adverse health effects are expected to develop if only small amounts (less than a mouthful) are swallowed. Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas. Not expected to cause an environmental hazard as a result of its intended use, disposal or incineration.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid dust formation. Avoid conditions that generate airborne dust in handling, transfer and cleanup. Keep away from heat, flame sparks and other ignition sources. Static charge may cause flash fire. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Store in a roofed and well-ventilated area. Keep container tightly closed. Store away from heat and light.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

If handling generates dust levels which cause irritation, or results in personal exposure exceeding the Occupational Exposure Standard (OES) of 10 mg/m^3 (8 hr time-weighted average [TWA] reference period) for total inhalable dust, then suitable approved dust respirator should be used.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Although this product does not present a significant skin concern, minimise skin contamination by following good industrial practice. Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: This product does not cause significant eye irritation or eye toxicity requiring special protection. Where there is significant potential for eye contact, wear chemical goggles and have eye flushing equipment available.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Diutan is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Joint FAO/WHO Expert Committee on Food Additives (1990). Toxicology Monograph 724 (Food Additive Series 28.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS. (2010). National Industrial Chemicals Notification and Assessment Scheme. Full Public Report. Diutan Gum https://www.industrialchemicals.gov.au/sites/default/files/SN20%20Public%20Report%20PDF.pdf

ETHYLENE GLYCOL

This dossier on ethylene glycol presents the most critical studies pertinent to the risk assessment of ethylene glycol in its use in hydraulic fracturing fluids. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Ethane-1,2-diol

CAS RN: 107-21-1

Molecular formula: $C_2H_6O_2$ ($HOCH_2CH_2OH$)

Molecular weight: 62.07 g/mol

Synonyms: Ethylene glycol; ethane-1,2-diol; 1,2-ethanediol, 2-hydroxyethanol; monoethylene glycol; MEG; glycol alcohol; EG

SMILES: C(CO)O

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Ethylene Glycol

Property	Value	Klimisch score	Reference
Physical state at 20oC and 101.3 kPa	Colourless and odourless syrupy liquid	2	ECHA
Melting Point	-13°C @ 101.3 kPa	2	ECHA
Boiling Point	197.4°C @ 101.3 kPa	2	ECHA
Density	1110 kg/m3@ 20°C	2	ECHA
Vapour Pressure	12.3 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-1.36 (calculated) @ 25°C	2	ECHA
Water Solubility	1000 g/L @ 20°C	2	ECHA
Flash Point	111°C	2	ECHA
Auto flammability	398°C	2	ECHA
Viscosity	16.1 mPa s @ 25°C	2	ECHA
Henry's Law Constant	0.133 @ 25°C (QSAR)	2	ECHA

III. ENVIRONMENTAL FATE SUMMARY

A. Summary

Ethylene glycol is readily biodegradable, and it is not expected to bioaccumulate. Ethylene glycol has low potential to adsorb to soil and sediment.

B. Biodegradation

Ethylene glycol was readily biodegradable in an OECD 301A test. After 10 days, degradation was 90-100% (ECHA) [Kl. score = 1]. There was 97% degradation after 20 days in a BOD test; and 96% degradation after 28 days in an OECD 301D test (Waggy et al., 1994; OECD, 2004a,b) [Kl. score = 2]. If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

The aerobic degradation of ethylene glycol was measured from grab river water samples at 4, 8 and 20°C. At 20°C, ethylene glycol was completely degraded in three days in all river waters tested; at 8°C, degradation was complete within 14 days. Degradation at 4°C was substantially slower, with degradation of < 20% after 14 days in river samples with limited suspended matter and a starting concentration of 10 mg/L (Evans and David, 1974).

C. Environmental Distribution

No experimental data are available for ethylene glycol. Using KOCWIN in EPISuite™ (USEPA, 2017), the estimated K_{oc} values from the molecular connectivity index (MCI) and from the log K_{ow} are 1 and 0.2239 L/kg, respectively.

Based upon these K_{oc} values, if released to soil, ethylene glycol is expected to have low potential for adsorption and a high potential for mobility. If released to water, based on its K_{oc} and high water solubility values, ethylene glycol is likely to remain in water and not adsorb to sediment. From the water surface, the substance will not evaporate into the atmosphere (ECHA).

D. Bioaccumulation

The calculated log K_{ow} for ethylene glycol is -1.36 (ECHA). The BCF for ethylene glycol in golden ide (*Leuciscus idus melanotus*) after three days of exposure was determined to be 10 (Freitag *et al.*, 1985). Bioaccumulation is not to be expected.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity. The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg. Ethylene glycol is not a skin irritant or a skin sensitiser in laboratory animals. In humans, ethylene glycol may cause skin irritation; there is also a low potential for skin sensitisation. It is not an eye irritant. The kidney is the primary target organ from repeated exposures. The proposed mode-of-action (MOA) for the kidney damage involves the formation of a precipitate or crystals from the ethylene glycol metabolite oxalic acid with calcium in the urine. Ethylene glycol is not genotoxic or carcinogenic to rodents. Ethylene glycol did not affect fertility in animal studies, but it did cause developmental effects. In rodents, the

developmental effects caused by oral doses of ethylene glycol include teratogenic effects (craniofacial and axial-skeletal malformations and variations). In contrast, no developmental toxicity was seen in rabbit studies. The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits. Based on a physiologically-based pharmacokinetic (PBPK) model for ethylene glycol, humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity.

B. Metabolism

Ethylene glycol is almost completely absorbed in laboratory animals by the oral route (OECD, 2004a; Frantz et al., 1996a). A range of 1-51% of ethylene glycol is absorbed by the dermal route based on *in vivo* studies in rodents (Frantz et al., 1996a,b).

The main metabolic pathway for metabolism of ethylene glycol is oxidation via alcohol dehydrogenases and aldehyde dehydrogenases. The main metabolites of ethylene glycol are carbon dioxide, oxalic acid and glycolic acid (OECD, 2004a).

The relevant metabolite for the repeated dose toxicity studies is oxalic acid, which is slowly transported from the liver to the kidneys, where is forms calcium-oxalate crystals (Corley et al., 2005a).

The relevant metabolite for the developmental toxicity seen in rodent, but not rabbit, studies appears to be glycolic acid. This metabolite can be reached at higher concentrations in rats than in rabbits (Carney et al., 1998).

A physiologically-based pharmacokinetic (PBPK) model has been developed for ethylene glycol. When internal dose surrogates were compared in rats and humans over a wide range of exposures, it has been concluded that humans are unlikely to achieve blood levels of glycolic acid necessary for developmental toxicity (Corley et al., 2005b).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,712 mg/kg (ECHA) [Kl. score = 2]. The 6-hour inhalation LC_{50} value for male and female rats was > 2.5 mg/L (Tyl et al., 1995a) [Kl. score = 2]. The dermal LD_{50} for male and female mice is > 3,500 mg/kg (Tyl et al., 1995b) [Kl. score = 2].

Following acute ingestion of ethylene glycol, the critical effects in humans in three subsequent stages are central nervous system toxicity, metabolic acidosis and kidney toxicity (ECHA). The lethal effects of ethylene glycol in human adults occur at oral doses of $\geq$ 1,600 mg/kg (Hess et al., 2004).

D. Irritation

Application of 0.5 mL of ethylene glycol to the skin of rabbits for 23 hours under occlusive conditions was not irritating (Guillot et al., 1982) [Kl. score = 2].

In a Human Repeated Insult Patch Test (HRIPT), ethylene glycol was applied to the skin for 24 hours under occlusive or semi-occlusive conditions for nine times during the induction phase. The induction phase was followed by a rest period of two weeks, followed by a 24-hour challenge on the sixth week of the study. Erythema was seen in a small proportion of the 401 subjects that completed the study. Under the conditions of the study, three subjects had reactions on challenge that were

indicative of possible irritation and/or low-level sensitisation. These three subjects were re-challenged under occlusive or semi-occlusive conditions one or two weeks later. Re-challenge testing was negative for one subject, but the other two subjects were judged to have irritant reactions to ethylene glycol since their reactions were similar or lesser compared to the skin responses observed during the induction period, and the skin reactions were not greater over time after the challenge or re-challenge (ECHA).

Instillation of 0.05 mL of ethylene glycol into the eyes of rabbits was not irritating (ECHA) [Kl. score = 2].

E. Sensitisation

Ethylene glycol was not a skin sensitiser to guinea pigs in a Magnusson and Kligman test (Kurihara et al., 1996) [Kl. score = 2]. In a HRIPT, ethylene glycol was considered to have a low potential for dermal sensitisation in humans (ECHA).

F. Repeated Dose Toxicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5% ethylene glycol for 13 weeks. Mortality was seen in the 5% males, but not in females. Mean weight gain was significantly decreased in the 2.5 and 5% males; there was no significant differences in female rats. Feed consumption was similar across all groups. A significant increase was seen in the left kidney weight in the 2.5 and 5% dose groups (both sexes); this was not seen in the right kidneys. Mean thymus ratio to terminal body weight was significantly decreased in the 5% males. Serum urea nitrogen levels were significantly increased in the 2.5 and 5% males, and significantly increased in the ≥ 0.32% females. Creatinine levels were decreased in the 0.32% groups and significantly increased in the 2.5 and 5% groups. The 2.5% and 5% male rats had kidneys that were rough, granular and/or pitted appearances. The 5% females showed nephrosis, and the 5% males had clusters of crystals in the brain. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2]

Male and female Sprague Dawley rats were given in their drinking water ethylene glycol for 90 days. The concentrations for females were 0, 0.5, 1.0, 2.0 or 4.0% (0, 597, 1,145, 3,087 or 5,744 mg/kg/day). The concentrations for males were 0, 0.25, 0.5, 1.0 or 2.0% (0, 205, 407, 947 or 3,134 mg/kg/day). In the 4% groups, there was mortality and decreased body weights (males only). Significant organ weights were noted only in males. Kidney weights were significantly increased in the 1% and 2% males; heart, liver and lung were significantly decreased in the 2% males. The 4% males also had a significant increase in the brain and gonads relative to body weights. Leukocyte levels were significantly decreased in the 0.5, 2 and 4% females, but not in males. Significant differences were noted in LDH, creatinine, ALT, calcium and glucose in the 1% males; and phosphorus, BUN and creatinine in the 2% males. There were significant increases in phosphorus in the 1% females and glucose in the 0.5 and 4% females. Kidney lesions were seen in the ≥ 2% females and in the ≥ 1% males, with the lesions more prominent in males than in females. The kidney changes consisted of tubular dilation, tubular degeneration, acute inflammation, birefringent crystals in tubules and pelvic epithelium. The NOAEL for this study is 407 mg/kg/day for males. The LOAEL for females is 597 mg/kg/day; a NOAEL was not established (Robinson et al., 1990) [Kl. score = 2]

Male and female B6C3F$_1$ mice were given in their feed 0, 0.32, 0.63, 1.25, 2.5 or 5.0% ethylene glycol for 13 weeks. There was no mortality and no treatment-related effect on mean weight gain and feed consumption. Organ/body weight ratios were similar across all groups. Serum urea nitrogen and creatinine levels were unaffected. Kidney effects were seen in the male, but not female, mice. Kidney lesions were observed in half of the 5% male mice and one mouse in the 2.5% dose level. Lesions were tubular dilation, cytoplasmic vacuolisation and regenerative hyperplasia of tubular cells. There was no evidence of crystal formation in the tubules. These changes were focal, randomly distributed and of minimal to mild severity. Hyaline degenerative of the liver was present in the centrilobular hepatocytes in all of the 2.5% and 5% males. These cells showed cytoplasmic accumulations of non bifringent, eosinophilic (hyaline), globular or crystalline material which resembled erythrocytes in size, shape and tinctorial properties. The NOAEL for this study is 1.25%, which was estimated to be 600 to 1,000 mg/kg/day (Melnick, 1984) [Kl. score = 2].

Male Fischer 344 and Wistar rats were given in their feed 0, 150, 500 or 1,000 mg/kg ethylene glycol for 16 weeks. At 1000 mg/kg, the following effects were seen: mortality in Wistar strain (2/10) with prior clinical observations of emaciation and dermal atonia and macroscopic findings of changes in kidneys (pale, calculi) and small seminal vesicles in these animals; mean body weight losses, lower mean body weights and mean cumulative body weight changes in Wistar strain (weeks 2 – 16); lower mean food consumption in Wistar strain; higher mean water consumption in both F344 and Wistar strains; lower mean specific gravity and higher mean total urine volume in both F344 and Wistar strains; macroscopic findings of pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weights in both F344 and Wistar strains; renal macroscopic findings of crystal nephropathy in Wistar and F-344 rats, with more severe nephropathy in Wistar strain than in the F344 strain. At 500 mg/kg, the following effects were seen: lower mean body weights (study weeks 3, 6-8 and 10-12) and mean cumulative body weight changes in the Wistar strain throughout the study with slightly lower mean food consumption throughout the study; higher mean water consumption in the Wistar strain; lower mean urine specific gravity and higher mean total urine volume in the Wistar strain; macroscopic findings in the Wistar strain consisting of predominantly pale kidneys, presence of calculi, rough surface and dilated pelvis; higher mean absolute and relative kidney weight in the Wistar strain; renal macroscopic findings of crystal nephropathy in Wistar and F-344 strains, with more severe nephropathy in the Wistar strain than in the F344 strain. The NOAEL in both the F344 and Wistar rats is 150 mg/kg/day (Cruzan et al., 2004) [Kl. score = 2].

Male Wistar rats were given in their feed 0, 50, 150, 300 or 400 mg/kg ethylene glycol for 12 months. There was mortality in the 300 and 400 mg/kg dose groups (5/20 and 4/20, respectively); the remaining 400 mg/kg animals were euthanised early (Day 203) due to excessive weight loss. The 300 mg/kg animals had increased water consumption and urine volume with decreased specific gravity, most likely due to osmotic diuresis. Calculi (calcium oxalate crystals) were found in the bladder and kidney pelvis in the ≥ 300 mg/kg animals. The ≥ 300 mg/kg rats that died prematurely had transitional cell hyperplasia with inflammation and haemorrhage of the bladder wall. Crystal nephropathy (basophilic foci, tubule or pelvic dilatation, birefringent crystals in the pelvic fornix, or transitional cell hyperplasia) was seen in all of the 400 mg/kg and most of the 300 mg/kg rats. These effects were not seen in the 50 or 150 mg/kg rats. Kidney oxalate levels, the metabolite responsible for the kidney toxicity, was not increased in the 50 and 150 mg/kg animals compared to the controls. The NOAEL for this study is 150 mg/kg/day (Corley et al., 2005) [Kl. score = 1].

Male and female Sprague-Dawley rats were given in their feed 0, 0.1, 0.2, 0.5, 1.0 or 4.0% ethylene glycol for two years. There was significant reduction in growth in the 4% males after week 16, and in the 1% males after week 70. The 4% females did not gain any weight past the first year of the study. Water consumption was double that of the controls in the 4% males that initiated soon after the

start of the study. The 1% males had significant increases in water consumption after 6 months and some increase was observed in the 0.5% males. Females only showed increased water consumption in the 4% group. There was 100% mortality in the 1 and 4% males, while mortality of additional dose levels were below that of the controls. There was 100% mortality in the 4% females, while the 1% females were similar to the controls; the 0.1, 0.2 and 0.5% females were increased compared to the controls. Since the 1 and 4% males and the 4% females all died before the study termination date, there are no data for these groups on terminal organ weight. For males, the terminal organ weights were decreased in all dose levels compared to the controls. For females, the organ weights were similar to the controls. The 1 and 4% males and females had kidneys with stones and crystals. The NOAEL for this study is 0.2% (data was insufficient to calculate the dose) (Blood, 1965) [Kl. score = 2].

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There were numerous adverse effects in the 1,000 mg/kg males and, to a lesser degree, in the 1,000 mg/kg females. The most remarkable effect was the production of urinary calculi in the kidneys, ureters and urinary bladders of the 1,000 mg/kg males, along with the presence of high levels of calcium oxalate in the urine. Increased incidences of tubular cell hyperplasia, tubular dilation, peritubular nephritis and focal granulomatous nephritis occurred in the 1,000 mg/kg males. Other significant findings in these males were markedly lower body weight gain, increased absolute and relative kidney weights, decreased absolute and relative liver weights, various hematopoietic changes and increased water consumption (likely a result of impaired kidney function). Histopathological changes in the 1,000 mg/kg males were mineralisation of the heart, lungs, stomach and vas deferens being the most noteworthy. The various adverse effects in these males resulted in reduced survival; there was increased mortality which became apparent by 8 months, with all males in this group died by month 16. Although calcium oxalate crystals were found in the urine of the 1,000 mg/kg females, no urinary calculi were seen. Absolute and relative kidney weights were increased in these rats. The most significant histopathologic finding in the 1,000 mg/kg females was fatty metamorphosis of the liver. There were transient changes in organ weights, erythroid parameters, water consumption rates and urine specific gravity in the 200 and 40 mg/kg rats; these effects were considered to be statistical artifacts attributable to chance. Focal soft mineralisation was observed in certain organs of the 200 and 40 mg/kg rats, which were considered to be the result of altered calcium metabolism associated with ingestion of ethylene glycol. The NOAEL for this study is considered to be 200 mg/kg/day (DePass et al., 1986a; ECHA) [Kl. score = 2].

Male and female B6C3F_1 mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) for 103 weeks. These concentrations are approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Survival, mean body weights and feed consumption was similar across all groups. There were no treatment-related clinical signs of toxicity. Liver lesions (males only) and arterial hyperplasia (females only) were observed at 12,500 ppm, but no adverse effects were observed at 6,250 ppm. The NOAEL for this study is 6,250 ppm in males, which corresponds to 1,500 mg/kg/day (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies in rodents or rabbits are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on ethylene glycol are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Ethylene Glycol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	+/-	-	2	McGregor et al. (1991)
Chromosomal aberration (CHO cells)	-	-	2	ECHA

*+, positive; -, negative

In Vivo Studies

A dominant lethal study was conducted in F344 rats given 0, 40, 200 or 1,000 mg/kg/day ethylene glycol in feed. There were slight increases in the dominant lethal mutation index in the high-dose and low-dose groups; these appear to be random occurrences and were not considered to be treatment-related. It was concluded that ethylene glycol was not genotoxic in this study (DePass et al., 1986b) [Kl. score = 2].

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their feed 0, 40, 200 or 1,000 mg/kg ethylene glycol for 24 months. There was increased mortality in the 1,000 mg/kg males, starting at 8 months and resulting in all males in this group dead by 16 months. Survival for the 1,000 mg/kg females and the 200 and 40 mg/kg males and females were similar to the controls. The incidence of mononuclear cell leukemia was statistically significantly higher in the 200 mg/kg males compared to the male controls, but not when compared to the pooled controls (males and females). Evaluation of the data by the method of Thomas et al. (2007), however, showed no treatment-related effect. It was concluded that ethylene glycol was not carcinogenic to rats in this study (DePass et al., 1986) [Kl. score = 2].

Male and female $B6C3F_1$ mice were given in their feed 0, 6,250 ppm (males only), 12,500 and 25,000 ppm (males and females) or 50,000 ppm (females only) ethylene glycol. These concentrations were approximately equivalent to 0, 1,500, 3,000, 6,000 or 12,000 mg/kg/day. Body weights, survival and incidence of tumours were similar between treated and control mice (NTP, 1993) [Kl. score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

I. Reproductive Toxicity

Ethylene glycol was assessed in a Reproductive Assessment by Continuous Breeding (RACB) protocol (Chapin and Sloane, 1997). The parental mice were administered ethylene glycol via drinking water during pre-mating exposure, cohabitation, pregnancy and lactation. The F_1 generation received prenatal exposure via maternal exposure during gestation, with the exposure continuing during lactation, weaning and mating of F_1 animals and production of an F_2 litter. The doses were 0, 0.25, 0.5 or 1% ethylene glycol, which corresponded to approximately 0, 410, 840 or 1,640 mg/kg/day. No adverse effects were noted in the parental animals at doses up to 1%. There was a small, but statistically significant, effects on the numbers of litters per fertile pair, the number of live pups per litter, and live pup weight in the 1% dose group. Neither the 0.25 nor 0.5% dose groups were significantly affected. The number of live pups per litter was lower in the treated groups, but differences were not statistically significant. Unusual facial features (i.e., shorter snout and wide-set eye) and skeletal defects (shortened frontal, nasal and parietal bones; fused ribs abnormally shaped or missing sternebrae, abnormally shaped vertebrae; and twisting of the spine) were noted on some of the offspring of the treated mice in the 1% group, but not in the controls. The parental NOAEL is 1% (approximately 1,640 mg/kg/day), and the NOAEL for reproductive toxicity is 0.5% (approximately 840 mg/kg/day (Lamb et al., 1985) [Kl. score = 2].

In a three-generation reproductive toxicity study, Fischer 344 rats were given in their diet 0, 40, 200 or 1,000 mg/kg/day ethylene glycol. There were no treatment-related effects on clinical signs of toxicity or survival in the parental animals. There were no significant effects on fertility index, gestation index, gestation survival for all three generations. Mean pup weights for each of the hree generations were similar between treated and control animals. The NOAEL for parental and reproductive toxicity is 1,000 mg/kg/day (DePass et al., 1986b) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Sprague-Dawley rats were dosed by oral gavage with 0, 50, 150, 500, 1,000 or 2,500 mg/kg ethylene glycol during gestational days (GD) 6-15. Maternal toxicity was observed in the 2,500 mg/kg group and consisted of significantly decreased body weights, increased water consumption, decreased uterine weights, increased kidney weights and increased relative liver weights. At 500 mg/kg, there were developmental effects, which included reduced foetal body weights, extra or missing ribs, missing arches and poor ossification in thoracic and lumbar centra. In the 2,500 mg/kg group, in addition to skeletal malformations, there was gastroschisis, hydrocephaly, lateral ventricle dilated (tissue depressed), umbilical hernia and atelectasis. The NOAELs for maternal and developmental toxicity are 1,000 and 500 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD rats were dosed by oral gavage with 0, 1,250 2,500 or 5,000 mg/kg ethylene glycol during GD 6-15. In the ≥ 2,500 mg/kg groups, the dams had increased relative kidney weights, decreased gravid uterine weight and increased water consumption. Maternal body weight gain was significantly decreased in the 1,250 mg/kg group. Live litter size was significantly decreased in the 5,000 mg/kg group and foetal body weights were decreased in the 1,250 and 5,000 mg/kg groups. Litters with malformed foetuses were observed in the ≥ 1,250 mg/kg groups. The LOAELs for maternal and developmental toxicity are 1,250 mg/kg/day; NOAELs were not established (Price et al., 1985) [Kl. score = 2].

Pregnant Fischer 344 rats were given by oral gavage 0, 40, 200 or 1,000 mg/kg ethylene glycol during GD 6-15. No maternal toxicity was observed at any dose level. There were no significant effects on preimplantation loss, foetal length, foetal weight, total implantations or litter size. There was an increased incidence of skeletal alterations in the 1,000 mg/kg group, which consisted of poorly ossified and unossified vertebral centra. No significant increases in the incidence of major malformations were observed. The NOAELs for maternal and developmental toxicity are 1,000 and 400 mg/kg/day (Maronpot et al., 1983) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 50, 150, 500 or 1,500 mg/kg ethylene glycol during gestational days (GD) 6 to 15. There was no maternal toxicity. At 1,500 mg/kg, there were reduced foetal body weights, fused ribs and arches, poor ossification in thoracic and lumbar centra and increased occurrence of an extra 14th rib. At 500 mg/kg, there was slight reductions in foetal body weight and increased incidences of extra ribs. The NOAELs for maternal and developmental toxicity were 1,500 and 150 mg/kg/day, respectively (Neeper-Bradley et al., 1995) [Kl. score = 2].

Pregnant CD-1 mice were dosed by oral gavage with 0, 750, 1,500 or 3,000 mg/kg ethylene glycol during GD 6 to 15. There was a significant decrease in maternal gain, gravid uterine weights and liver weights in the 1,500 mg/kg group. A decreased number of implantation sites per litter was observed in the 1,500 mg/kg group. Significant decrease in liver litter size was observed in the 3,000 mg/kg group and decreased foetal body weights were seen at ≥ 750 mg/kg. Litters with a significant increase in malformed foetuses were observed in the ≥ 750 mg/kg groups. There was a significant dose-related increase in post-implantation loss per litter, though there were no significant pairwise comparisons. The NOAEL for maternal toxicity is 750 mg/kg/day. The LOAEL for developmental toxicity is 750 mg/kg/day; the NOAEL was not established (Price et al., 1985) [Kl. score = 2].

In a short-term reproductive and developmental toxicity screen test, male and female Swiss Crl:CD-1 mice were allowed to mate over a three-day period. The males were dosed by oral gavage from study Day 3 to study Day 20. The Group A females were exposed throughout the 21-day test period; the Group B females were exposed during GD 8-14. The doses were 0, 250, 700 or 2,500 mg/kg ethylene glycol. The Group A females were sacrificed after 19 days of treatment, and the Group B females were allowed to litter and rear to postnatal day (PND) 4. There was no maternal or paternal toxicity. The 2,500 mg/kg females in Group A had significantly fewer liver implants and more dead implants. The 2,500 mg/kg in Group B had significantly lower total litter weights on PND 1 and 4. The NOAELs for parental and developmental toxicity are 2,500 and 700 mg/kg/day (Harris et al., 1992) [Kl. score = 2].

In a Chernoff/Kavlock assay, pregnant CD-1 mice were dosed by oral gavage with 0 or 11,090 mg/kg ethylene glycol during GD 7-14. The females were allowed to litter and rear to PND 3. Ten percent of the maternal animals died. The number of surviving pups per litter (40% survived), birth weight and pup weight gain were reduced. The LOAELs for maternal and developmental toxicity are 11,090 mg/kg; NOAELs were not established (Schuler et al., 1984; Hardin et al., 1987) [Kl. score = 2].

Pregnant female New Zealand White rabbits were dosed by oral gavage with 0, 100, 500, 1,000 or 2,000 mg/kg ethylene glycol on GD 6 to 19. At 2,000 mg/kg, eight of the 17 does (42.1%) died. Maternal body weights and body weight gain were similar across all groups. There was no developmental toxicity. The NOAEL for maternal toxicity is 1,000 mg/kg/day. The NOAEL for developmental toxicity is 2,000 mg/kg/day, the highest dose tested (ECHA) [Kl. score = 2].

Pregnant female CD rats were dosed by oral gavage with 0, 250, 1,250 or 2,250 mg/kg ethylene glycol on GD 6 to 20. At 2,250 mg/kg, maternal body weight, body weight gain, kidney weight and postpartum uterine weight were significantly reduced. At 1,250 mg/kg, the gestational period was

lengthened and maternal kidney histopathological effects were noted. Developmental toxicity was noted in the 2,250 mg/kg group and included reduced pup weight, reduced viability and increased malformations (primarily hydrocephaly and abnormalities of the axial skeleton). No developmental toxicity was seen in the 1,250 mg/kg group. The NOAEL for maternal and developmental toxicity is 250 mg/kg/day (ECHA) [Kl. score = 2].

Inhalation

Pregnant female CD rats were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. There was no treatment-related mortality; a dose-related increased in clinical signs (red fur discoloration on the head and neck) was noted, which was considered to be a non-specific indication of stress. Body weights and body weight gain were unaffected by treatment. There was some evidence of treatment-related reductions in ossification of the foetal skeleton at 1,000 and 2,500 mg/m^3 (considered as fetotoxicity). The NOAECs from inhalation exposure cannot be determined due to confounding oral exposure during whole-body exposure. However, there was no maternal or embryotoxicity at 150 mg/m^3 and no teratogenicity at any aerosol concentration tested (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (whole-body) to 0, 150, 1,000 or 2,500 mg/m^3 ethylene glycol aerosol 6 hours/day on gestational days 6 to 15. Reduced maternal body weight was observed in the 2,500 mg/m^3 group on GD 12,15 and 18 and in the 1,000 mg/m^3 group on GD 18. Reduced maternal weight gain was also seen during GD 6-12, 6-15 and GD 6-18 for the ≥ 1000 mg/m^3 groups and for GD 5-18 for the 2,500 mg/m^3 group. Terminal body weights were reduced in the ≥ 1,000 mg/m^3 groups. Gravid uterine weight was also reduced in the ≥ 1,000 mg/m^3 groups, so that body weight corrected for gravid uterine weight was unaffected. The number of viable implantations per litter was reduced at 2,500 mg/m^3. The number of non-viable implantations per litter was elevated at ≥ 1,000 mg/m^3 because of a significant increase in late resorptions at 1,000 mg/m^3, and a significant increase in late resorptions and in dead foetuses at 2,500 mg/m^3. The number of early resorptions at 2,500 mg/m^3 was also elevated but not statistically. foetal body weights per litter (male, female and total) were reduced at ≥ 1,000 mg/m^3. There was a significant increase in the incidence of a number of external, visceral and skeletal malformation, as well as skeletal variations, at ≥ 1,000 mg/m^3. There was no observable maternal or developmental toxicity at 150 mg/m^3. However, a NOAEC cannot be determined because of the amount of ethylene glycol that may have been ingested from the presence of ethylene glycol on the fur (Tyl et al., 1995a) [Kl. score = 2].

Pregnant female CD-1 mice were exposed by inhalation (nose-only) to 0, 500, 1,000 or 2,500 mg/m^3. The study also included a group exposed to 2,100 mg/m^3 (not discussed here). Reduced maternal body weight gain were seen in the 2,500 mg/m^3 for GD 9-12, 12-15, 6-15 and 0-18. Absolute kidney weights were increased in the ≥ 1,000 mg/m^3 groups. foetal body weights per litter were significantly reduced for the 2,500 mg/m^3. In the 2,500 mg/m^3, there was a significant increase in one skeletal malformation (fusion of the ribs) and an increased incidence of skeletal variations. No other teratogenic effects were observed. The NOECs for maternal and developmental toxicity are 500 and 1,000 mg/m^3, respectively (Tyl et al., 1995c) [Kl. score = 2].

Dermal

Pregnant CD-1 mice were administered by dermal applications of 0, 400, 1,677 or 3,549 mg/kg ethylene glycol 6 hours/day on GD 6-15. There was minimal, if any, treatment-related maternal toxicity. Copora lutea, total implants, percentage of live foetuses per litter, foetal body weights and incidence of external or visceral malformations were unaffected by treatment. There was, however,

a significant increase in two skeletal variations in the 3,549 mg/kg group. The NOAELs for maternal and developmental toxicity were considered to be 3,549 mg/kg/day (Tyl et al., 1995b) [Kl. score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for ethylene glycol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The NOAEL from a 24-month rat dietary study was reported to be 200 mg/kg/day based on kidney lesions in male F344 rats at 1,000 mg/kg/day (DePass et al., 1986b). A subsequent 12-month rat dietary study using male Wistar rats reported a NOAEL of 150 mg/kg/day also based on kidney toxicity at 300 mg/kg/day and higher (Corley et al., 2008). The Wistar rat strain was shown to be more sensitive (approximately three-fold) to the kidney toxicity of ethylene glycol than F344 rats (Cruzan et al., 2004). The NOAEL of 150 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Snellings et al. (2013) derived an oral reference dose for ethylene glycol using benchmark dose modelling, with toxicokinetic (PBPK modelling) and toxicodynamic data. The human equivalent dose ($[BMDL_{05}]_{HED}$) was calculated to be 150 mg/kg/day.

Oral RfD = $[BMDL_{05}]_{HED}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 1
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 150/(1 x 10 x 1 x 1 x 1) = 150/10 = 15 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (15 x 70 x 0.1)/2 = 53 mg/L

B. Cancer

Ethylene glycol was not carcinogenic to rats and mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ethylene glycol does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Ethylene glycol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on ethylene glycol.

Table 3: Acute Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	>72,860	1	Pillard (1995)
Oncorhynchus mykiss	96-hour LC_{50}	22,810 24,591	2	OECD (2004a,b)
Daphnia magna	48-hour EC_{50}	>100	1	ECHA
Daphnia magna	48-hour EC_{50}	46,300	2	Gersich et al. (1986)
Ceriodaphnia dubia-affinis	48-hour EC_{50}	25,800 (20°C) 10,000 (24°C)	2	Cowgill et al. (1985)
Daphnia magna	48-hour EC_{50}	46,300 (20°C) 51,000 (24°C)	2	Cowgill et al. (1985)
Selenastrum capricornutum	96-hour IC_{50} NOEC	10,940 10,000	2	Pillard and DuFresne (1999)

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies conducted on ethylene glycol.

Table 4: Chronic Aquatic Toxicity Studies on Ethylene Glycol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	7-day NOEC	15,380	2	Pillard (1995)
Ceriodaphnia dubia	7-day NOEC (reproduction)	8,590	2	Pillard (1995)
Pseudokirchneriella subcapitata	72-hr NOEC	>100 *	2	ECHA

*Read-across to pentaethylene glycol (CAS No. 4792-15-8)

C. Terrestrial Toxicity

No guideline studies have been conducted on ethylene glycol.

D. Calculation of PNEC

The PNEC calculations for ethylene glycol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (22,810 mg/L), *Daphnia* (>100 mg/L), and algae (10,940 mg/L). NOEC values from long-term studies are available for fish (15,380 mg/L), invertebrates (8,590 mg/L) and algae (10,000 mg/L). On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported E(L)C_{50} value of 100 mg/L for fish. The E(L)C_{50} value is used because the value for fish is lower than the NOEC values for all three trophic levels. The $PNEC_{aquatic}$ is 10 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.4 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.82/1280) \times 1000 \times 10$
$= 6.4$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [(0.2 \times Kp_{sed})/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 0.04/1000 \times 2400]$
$= 0.82\ m^3/m^3$

Where:

Kp_{sed} = solid-water partition coefficient (L/kg)

BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]

$Kp_{sed} = K_{oc} \times f_{oc}$

= 1 x 0.04

= 0.04 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.13 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$

= (0.02/1500) x 1000 x 10

= 0.13 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)

BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]

$Kp_{soil} = K_{oc} \times f_{oc}$

= 1 x 0.02

= 0.02 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for ethylene glycol calculated from EPISUITE™ using the MCI is 1 L/kg.

F_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ethylene glycol is readily biodegradable and thus does not meet the screening criteria for persistence.

The measured BCF in fish is 10. Thus, ethylene glycol does not meet the criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on ethylene glycol are > 0.1 mg/L. The acute $E(L)C_{50}$ values from the acute aquatic toxicity studies on ethylene glycol are > 1 mg/L. Thus, ethylene glycol does not meet the criteria for toxicity.

The overall conclusion is that ethylene glycol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

STORE Category 2 (target organ: kidney)

B. Labelling

Warning

A. Pictogram



IX. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention.

Ingestion

Rinse mouth with water and then drink a glass of water. Get medical attention. Never give anything by mouth to an unconscious person.

Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

B. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Handle in accordance with good industrial hygiene and safety practice.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

For large amounts: dike spillage and pump off product. For residues: pick up with suitable absorbent material. Dispose of contaminated material as prescribed.

C. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

D. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standards for ethylene glycol in Australia is as follows: 10 mg/m^3 as an 8-hour TWA for ethylene glycol (particulate); 20 ppm (52 mg/m^3) as an 8-hour TWA for ethylene glycol (vapour). There is also a skin notation indicating that absorption through the skin may be significant source of exposure.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

X. TRANSPORT INFORMATION

Ethylene glycol is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Blood, F.R. (1965). Chronic toxicity of ethylene glycol in the rat. Food Cosmet. Toxicol. 3: 229-234.

Carney, E.W., Pottenger, L.H., Bartels, M.J., Jaeckh, R., and Quast, J.F. (1998). Comparative pharmacokinetics and metabolism of ethylene glycol in pregnant rats and rabbits. Toxicol. Lett. 95: 208.

Chapin, R.E. and R.A. Sloane. (1997). Reproductive assessment by continuous breeding: evolving study design and summaries of ninety studies. Environ Health Perspect. 1997 Feb; 105(Suppl 1): 199–205.

Corley, R.A., Meek, M.E., and Carney, E.W. (2005a). Mode of action: oxalate crystal-induced renal tubule degeneration and glycolic acid-induced dysmorphogenesis – renal and developmental effects of ethylene glycol. Crit. Rev. Toxicol. 35: 691-702.

Corley, R.A., Bartels, M.J., Carney, E.W., Weitz, K.K., Soelberg, J.J., and Gies, R.A. (2005b). Development of a physiologically based pharmacokinetic model for ethylene glycol and its metabolite, glycolic acid, in rats and humans. Toxicol. Sci. 85: 476-490.

Corley, R.A., Wilson, D.M., Hard, G.C., Stebbins, K.E., Bartels, M.J., Soelberg, J.J., Dryzga, M.D., Gingell, K.E and Snellings, W.M.(2008). Dosimetry considerations in the enhanced sensitivity of male Wistar rats to chronic ethtlene glocol-induced nephrotoxicity. Toxicology and Applied Pharmacology. Volume 228, Issue 2: 165-178.

Cowgill, U.M., Takahash, I.T., and Applegath, S.L. (1985). A comparison of the effect of four benchmark chemicals on Daphnia magna and Ceriodaphnia dubia-affinis tested at two different temperatures. Environ. Toxicol. Chem. 4: 415-422.

Cruzan, G., Corley, R.A., Hard, G.C., Mertens, J.J., McMartin, K.E., Snellings, W.M., Gingell, R., and Deyo, J.A. (2004). Subchronic toxicity of ethylene glycol in Wistar and F-344 rats related to metabolism and clearance of metabolites. Toxicol Sci. 81: 502-11.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DePass, L.R., Garman, R.F., Woodside, M.D., Giddens, W.E., Maronpot, R.R., and Weil, C.S. (1986a). Chronic toxicity and oncogenicity studies of ethylene glycol in rats and mice. Fundam. Appl. Toxicol. 7: 547-565.

DePass, L.R., Woodside, M.D., Maronpot, R.R., and Weil, C.S. (1986b). Three-generation reproduction and dominant lethal mutagenesis studies with ethylene glycol in the rat. Fundam. Appl. Toxicol. 7: 566-572.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Evans, W.H., and David, E.J. (1974). Biodegradation of mono-, di-, and triethylene glycols in river waters under controlled laboratory conditions. Water Res. 8: 97-100.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996a). Pharmacokinetics of ethylene glycol. I. Plasma disposition after single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Drug Metab. Dispos. 24: 911-921.

Frantz, S.W., Beskitt, J.L., Grosse, C.M., Tallant, M.J., Dietz, F.K., and Ballantyne, B. (1996b). Pharmacokinetics of ethylene glycol. II. Tissue distribution, dose dependent elimination, and identification of urinary metabolites following single intravenous, peroral, or percutaneous doses in female Sprague-Dawely rats and CD-1 mice. Xenobiotica 26: 1195-1220.

Freitag, D., Ballhorn, L., Geyer, H., and Korte, F. (1985). Environmental hazard profile of organic chemicals. Chemosphere 14: 1589-1616.

Gersich, F.M., Blanchard, F.A., Applegath, S.L., and Park, C.N. (1986). The precision of Daphnid (Daphnia magna Straus, 1820) static acute toxicity tests. Arch. Environ. Contam. Toxicol. 15: 741-749.

Guillot, J.P., Martini, M.C., Giauffret, J.Y., Gonnet, J.F., and Guyot, J.Y. (1982). Safety evaluation of some humectants and moisturizers used in cosmetic formulations. Int. J. Cosmetic Science 4: 67-80.

Hardin, B.D., Schuler, R.L., Burg, J.R., Booth, G.M., Hazelden, K.P., MacKenzie, K.M., Piccirillo, V., Jr, and Smith, K.N. (1987). Evaluation of 60 chemicals in a preliminary developmental toxicity test. Terat. Carcinogen. Mutagen. 7: 29-48.

Harris, M.W., Chapin, R.E., Lockhart, A.C., and Jokinen, M.P. (1992). Assessment of a short-term reproductive and developmental toxicity screen. Fundam. Appl. Toxicol. 19: 186-196.

Hess, R., Bartels, M.J., and Pottenger, L.H. (2004). Ethylene glycol: an estimate of tolerable levels of exposure based on a review of animal and human data. Arch. Toxicol. 78: 671-680.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Kurihara, A., Manabe, A., Katsuno, K., Itoh, K., Hisamitsu, H., Wakumoto, S., and Yoshida, T. (1996). Evaluation of skin irritation and sensitization of two diol solutions used as experimental dentin primers in humans and guinea pigs. Dent. Mater. J., 15: 226-232.

Lamb, J.C., IV, Maronpot, R.R., Gulati, D.K., Russel, V.S., Hommel-Barnes, L., and Sabharwa, l. P.S. (1985). Reproductive and developmental toxicity of ethylene glycol in the mouse. Toxicol. Appl. Pharmacol. 81: 100-112.

McGregor, D.B., Brown, A.G., Howgate, S., McBride, D., Riach, C., and Caspary, W.J. (1991). Responses of the L5178Y mouse lymphoma cell forward mutation assay. V: 27 coded chemicals. Environ. Mol. Mutagen. 17: 196-219.

Melnick, R.L. (1984). Toxicities of ethylene glycol and ethylene glycol monoether in Fischer 344/N rats and B6C3F1 mice. Environ. Health Perspect. 57: 147-155.

Neeper-Bradley, T.L., Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco P.E. (1995). Determination of a no-observed-effect level for developmental toxicity of ethylene glycol administered by gavage to CD rats and CD-1 mice. Fundam. Appl. Toxicol. 27: 121-130.

National Toxicology Program [NTP]. (1993). Toxicology and Carcinogenesis Studies of Ethylene Glycol in B6C3F1 Mice (Feed Studies). National Toxicology Program Technical Report Series No. 413.

OECD. (2004a). SIDS Dossier on the HPV Chemical Ethylene Glycol (CAS No. 107-21-1).

OECD. (2004b). SIDS Initial Assessment Report on the Ethylene Glycol Category: Ethylene Glycol (CAS No. 107-21-1), Diethylene Glycol (CAS No. 111-46-6), Triethylene Glycol (CAS No. 112-27-6), Tetraethylene Glycol (CAS No. 112-60-7), Pentaethylene glycol (CAS No. 4792-15-8).

Pillard, D. (1995). Comparative toxicity of formulated glycol deicers and pure ethylene and propylene glycol to Ceriodaphnia dubia and Pimephales promelas. Environ. Toxicol. Chem. 14: 311-315.

Pillard, D.A. and DuFresne, D.L. (1999). Toxicity of formulated glycol deicers and ethylene and propylene glycol to lactuca sative, lolium perenne, selenastrum capricornutum, and lemna minor. Arch Environ. Contam. Toxicol. 37(1):29-35.

Price, C.J., Kimmel, C.A., Tyl, R.W., and Marr, M.C. (1985). The developmental toxicity of ethylene glycol in rats and mice. Toxicol. Appl. Pharmacol. 81: 113-127.

Robinson, M., Pond, C.L., Laurie, R.D., Bercz, J.P., Henningsen, G., and Condie L.W. (1990). Subacute and subchronic toxicity of ethylene glycol administered in drinking water to Sprague-Dawley rats. Drug Chem. Toxicol .13: 43-70.

Schuler, R.L., Hardin, B.D., Niemeier, R.W., Booth, G., Hazelden, K., Piccirillo, V., and Smith, K. (1984). Results of testing 15 glycol ethers in a short-term in vivo reproductive toxicity assay. Environ. Health Perspect. 57: 141-146.

Snellings, W.M., Corley, R.A., McMartin, K.E., Kirman, C.R., and Bobst, S.M. (2013). Oral reference dose for ethylene glycol based on oxalate crystal-induced renal tubule degeneration as the critical effect. Regul. Toxicol. Pharmacol. 65: 229-241.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P. (2007). A review of large granular lymphocytic leukemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Fait, D.L., Savine, T.A., Dodd, D.E., Klonne, D.R., and Pritts, I.M. (1995a). Evaluation of the developmental toxicity of ethylene glycol aerosol in the CD rat and CD-1 mouse by whole-body exposure. Fundam. Appl. Toxicol. 24: 57-75.

Tyl, R.W., Fisher, L.C., Kubena, M.F., Vrbanic, M.A., and Losco, P.E. (1995b). Assessment of the developmental toxicity of ethylene glycol applied cutaneously to CD-1 mice. Fundam. Appl. Toxicol. 27: 155-166.

Tyl, R.W., Ballantyne, B., Fisher, L.C., Dodd, D.E., Klonne, D.R., Pritts, M., and Losco, P.E. (1995c). Evaluation of the developmental toxicity of ethylene glycol aerosol in CD-1 mice by nose-only exposure. Fundam. Appl. Toxicol. 27: 49-62.

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Waggy, G.T., Conway, R.A., Hansen, J.L., and Blessing, R.I. (1994). Comparison of 20-d BOD and OECD closed-bottle biodegradation tests. Environ. Toxicol. Chem. 13: 1277-1280.

GELATINS

This dossier on gelatins presents the most critical studies pertinent to the risk assessment of gelatins in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Gelatins

CAS RN: 9000-70-8

Molecular formula: Not applicable as substance is a UVCB whose specific chemical composition is dependent on formulation processes.

Molecular weight: Depending on the specific commercial use, the molecular weight can range from 72 to 132 kDaltons (i.e., 72,000 to 132,000 g/mol) (Farrugia et. al., 1998)

Synonyms: None identified.

SMILES: Not applicable.

II. PHYSICAL AND CHEMICAL PROPERTIES

Gelatin is a white to yellow, translucent powder. It is hydrolysed and partially degraded collagen obtained by acid, alkaline or enzymatic hydrolysis. It is a polypeptide. Depending on the source of collagen and the method of its manufacturing process of recovery from collagen, gelatin contains an average of the following amino acids: glycine 21%, proline 12%, hypoproline 12%, glutamic acid 10%, alanine 9%, arginine 8%, aspartic acid 6%, lysine 4%, serine 4%, leucine 3%, valine 2, phenylalanine 2%, threonine 2%, isoleucine 1%, hydroxylysine 1%, histidine <1% and tyrosine <0.5% (Gorgieva and Kokol, 2011).

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Gelatins are readily biodegradable; they are not expected to bioaccumulate or adsorb to soil.

B. Biodegradation

As a natural polymer, gelatin is expected to be readily biodegradable by most proteases when environmental conditions are adequate. While high molecular weight polymer degradation rates are generally thought to be low, the biopolymeric nature of gelatin in a variety of cross-linked forms appears to result in rapid biodegradation (e.g., 3-10 days) in the environment (Patel et. al., 2000).

Gelatin, as a rapidly biodegradable protein, is a rich source of amino acids and other nutrients such as nitrogen and carbon for bacteria and fungi. The increased bioavailability of nutrients could lead to a significant increase in biological oxygen demand (BOD) as a result of degradation of gelatin and the stimulated growth of microorganisms. High BOD will deplete local dissolved oxygen concentrations

when gelatin or its breakdown products are released into the aquatic environment in sufficient quantities relative to the volume of the receiving water body. This depletion of oxygen has the potential to place significant stress on some organisms within the aquatic environment (DoEE, 2017).

C. Environmental Distribution

Given the hydrophilic nature of gelatin it is unlikely that this biopolymer would adsorb to the soil or sediment.

D. Bioaccumulation

The potential for bioaccumulation is low. Based on the biological properties and the environmental fate of gelatin, especially the rapid biodegradation, prolonged exposure of aquatic organisms to the biopolymer will be highly unlikely (DoEE, 2017).

IV. HUMAN HEALTH HAZARD ASSESSMENT

There is no data on the human health hazard for this substance. However, based on its biopolymeric nature and uses in foods and medicines, the human health toxicity concern is expected to be very low.

NICNAS has assessed gelatin in an IMAP Tier 1 assessment and it was concluded that it poses no unreasonable risk to the environment[1]. In addition, based on an assessment of human health and environmental hazards, NICNAS also identified gelatin as a chemical of low concern to the environment (NICNAS, 2017 and DoEE, 2017). Chemicals of low concern are unlikely to have adverse environmental effects or be a concern to human health if they are released to the environment from coal seam gas operations.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference and drinking water guidance values have not been derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Gelatin does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no aquatic toxicity studies on gelatin. However, it is expected to have low concern for aquatic toxicity since any gelatin released into aquatic ecosystems will be rapidly degraded by microorganisms through enzymatic digestion to the individual amino acids or short peptides. If sufficient quantities of gelatin were abruptly released into a water body, this could cause temporary changes in water quality for local organisms, such as reduced dissolved oxygen concentrations (DoEE, 2017).

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9000-70-8%2C+

B. Aquatic Toxicity

No aquatic toxicity data was available.

C. Terrestrial Toxicity

No relevant studies were available.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Gelatins are readily biodegradable; thus, it does not meet the screening criteria for persistence.

The rapid degradation and expected lability to enzymatic degradation suggests gelatins will not meet the screening criteria for bioaccumulation.

There are no aquatic toxicity studies on gelatins. It is expected to have low concern for aquatic toxicity because of its bio-composition (e.g., various amino acids and crosslinked substituents) and rapid degradation rates in the environment. Thus, gelatin does not meet the screening criteria for toxicity.

The overall conclusion is that gelatin is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

Based on the low concern of this substance, and according to the majority of notifications provided by companies to ECHA under the Classification, Labelling and Packaging of Substances and Mixtures Regulation No 1272/2008, no hazards have been classified.

X. SAFETY AND HANDLING

Based on the low concern status of this substance, no specific safety or handling precautions are relevant.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy (DoEE). (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Farrugia, C.A., Farrugia, I.V. and Groves, M.J. (1998). Comparison of the Molecular Weight Distribution of Gelatin Fractions by Size-exclusion Chromatography and Light Scattering. Pharm. Pharmacol. Commun. 1998, 4: 559-562

Gorgieva, S, and Kokol V. (2011). 'Collagen- vs. Gelatine-Based Biomaterials and Their Biocompatibility: Review and Perspectives', in: Pignatello R (ed) Biomaterials applications for nanomedicine, INTECH, retrieved from http://www.intechopen.com/books/biomaterials-applications-for-nanomedicine.

Klimisch, H. J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol Pharmacol. 25:1-5.

NICNAS. (2017). Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra

Patel, Rajaram dattu, Dalev, P.G., and Mark, J.E. (2000). Biodegradation of chemically modified gelatin films in lake and river waters. Journal of Applied Polymer Science 76(1):29 – 37

GLUTARALDEHYDE

This dossier on glutaraldehyde presents the most critical studies pertinent to the risk assessment of glutaraldehyde in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from NICNAS (1994) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Glutaraldehyde

CAS RN: 111-30-8

Molecular formula: $C_7H_8O_2$

Molecular weight: 100.12 g/mol

Synonyms: Pentanedial; glutaral; glutaric dialdehyde; 1,3-diformylpropane; 1,5-pentanedial; glutaric aldehyde; glutaric acid dialdehyde; dioxopentane; glutardialdehyde; 1,5-pentanedione; Algicide®C

SMILES: C(CC=O)CC=O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Glutaraldehyde

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa*	Sweetish smelling, clear water liquid	1	ECHA
Melting Point*	-33°C (pressure not provided)	1	ECHA
Boiling Point*	101.5°C @ 98.71 kPa	1	ECHA
Density*	1,130 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure*	21 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})*	-0.36 @ 23°C and pH 7	1	ECHA
Water Solubility*	Miscible @ 20°C	2	ECHA
Flash Point*	Not measurable	1	ECHA
Auto flammability*	395°C @ ~1,000hPa	1	ECHA
Viscosity*	12.75 mm^2/s (static) at 25°C	1	ECHA
Henry's Law Constant	0.011 Pa m^3/mol at 25°C [QSAR]	2	ECHA

*ca. 50% glutaraldehyde solution (in water)
1 ppm = 4.095 mg/m3
1 mg/m3 = 0.244 ppm

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Glutaraldehyde is considered readily biodegradable. It is also expected to have a low potential for bioaccumulation. The K_{oc} values for glutaraldehyde indicate that it will have low potential for adsorption to suspended solids and sediment in water and moderate adsorption to soil. Glutaraldehyde is not expected to undergo hydrolysis in the environment. Overall, glutaraldehyde shows limited persistence in the environment.

B. Partitioning

In an OECD TG 111 test (hydrolysis as a function of pH), glutaraldehyde was hydrolytically stable at pH 4 and pH 7 but decomposed at pH 9 (ECHA) [Kl. score = 2].

Photolytic degradation of glutaraldehyde occurred in water under sensitised conditions: the half-life was 18 days when equivalent to 36 days of natural sunlight (12 hours/day; sensitised acetone system); and 49 days when equivalent to 34 days of natural sunlight (12 hours/day; sensitised acetonitrile system). There was no photodegradation of glutaraldehyde under darkness or non-sensitised conditions (ECHA) [Kl. score = 2].

C. Biodegradation

Glutaraldehyde was considered readily biodegradable in an OECD 301A (DOC die away test). Degradation was 90-100% in 28 days (ECHA) [Kl. score = 1].

In a simulation test involving aerobic sewage treatment [activated sludge units] (OECD TG 303A), glutaraldehyde degraded 97% after 73 days based on DOC removal (ECHA) [Kl. score = 1].

In an aerobic aquatic metabolism test, [^{14}C]-glutaraldehyde had a half-life of 10.6 hours in the water/sediment system. A minor transformation product was glutaric acid: the maximum yield was 18.9 to 21.5% at 12 hours, which then declined rapidly to 10.1 to 11% by 24 hours; and was not observed at the end of the study period in the aqueous phase (ECHA) [Kl. score = 1].

In an anaerobic aquatic metabolism test, [^{14}C]-glutaraldehyde was rapidly metabolised with the first-order half-life being 7.7 hours. Glutaraldehyde was transformed to 5-hydroxypentanal (ca 37% of applied radioactivity) on day 1; after that, it declined to < 10%; it was not detected at all after 30 days. The second stable transformation product was 1,5-pentanediol (35% of radioactivity on Day 1), which accounted for 70% of the radioactivity at the end of the test. A minor transformation product was a compound formed via Aldol condensation, cyclisation and dehydration. This compound accounted for about 10-20% of total radioactivity from Day 1 onwards (ECHA) [Kl. score = 1].

In an aerobic soil metabolism test, the half-life of the degradation of [^{14}C]-glutaraldehyde was calculated to be 1.7 days, indicating rapid degradation in soil by microbial biotransformation. Degradation products were measured but not identified (ECHA) [Kl. score = 1].

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

The organic carbon/water partition coefficients (K_{oc}) values were determined for sediment and four types of soil. The values are as follows: 120 for sediment; 210 for sandy loam; 500 for silty clay loam; 340 for silt loam; and 460 for loamy sand (ECHA; Leung, 2001) [Kl. score = 1].

Based on these K_{oc} values, glutaraldehyde is considered to be moderately mobile in soil. If released to water, based on these K_{oc} values and its water solubility, it has moderate potential for adsorption to suspended solids or sediments.

E. Bioaccumulation

Glutaraldehyde is not expected to bioaccumulate. The measured log K_{ow} at pH 5, 7 and 9 are -0.41, -0.36 and -0.80, respectively (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has moderate-to-high acute toxicity by the oral route, low-to-moderate toxicity by the dermal route, and moderate-to-high toxicity by the inhalation route. Acute inhalation exposure may cause respiratory irritation. Glutaraldehyde is corrosive to the skin and eyes; it is also a skin and respiratory sensitiser. Repeated oral exposures via drinking water to rats have resulted in general systemic toxicity, but no target organ effects. In contrast, the upper respiratory tract, particularly the nasal cavity, is the target organ in rodents from repeated inhalation exposure. Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests, whereas the *in vivo* studies consistently show no genotoxic activity. Glutaraldehyde is not a reproductive toxicant; developmental toxicity can occur at maternally toxic doses, but there is no teratogenicity.

B. Toxicokinetics

Dermal Absorption

[1,5-^{14}C]-glutaraldehyde was applied to the skin of male and female F344 rats. Doses were 0.75% and 7.5%: this corresponds to approximately 6.5 and 63 mg/kg for males; and approximately 8.7 and 102 mg/kg for females. The dermal absorption data are presented in Table 2. The results indicate that glutaraldehyde has a low rate of absorption by the dermal route (ECHA).

Table 2: Dermal Absorption Data in Rats on Glutaraldehyde (ECHA)

Sex	Absorption rate constant/hr		% of applied dose	
	Low Dose	High Dose	Low Dose	High Dose
Males	1.5	0.7	0.7	1.3
Females	1.8	0.9	0.3	2.1

An *in vitro* percutaneous absorption study was conducted on glutaraldehyde using excised skin from rats, rabbits, mice, guinea pigs and humans. The skin samples were placed in a flow-through skin penetration chamber, and [^{14}C]-glutaraldehyde was added at doses of 0.75% and 7.5%. The results are presented in Table 3. Glutaraldehyde did not penetrate any of the skin samples to a significant degree, suggesting that only minimal amounts of glutaraldehyde may be available for systemic

uptake and distribution after skin exposure. The results also show that skin absorption was greater for the animal species used in toxicity tests than human skin (ECHA; Frantz et al., 1993).

Table 3: *In vitro* Percutaneous Absorption (mg/cm^2) of Glutaraldehyde (ECHA; Frantz et al., 1993)

Species	Low Dose	High Dose
Animal*	0.006	0.08
Human	0.002	0.02

*Percutaneous absorption in rats, mice, guinea pigs, mice and rabbits were similar to each other and were reported as a single value.

C. Acute Toxicity

The oral LD_{50} values are: 123 to 820 mg/kg in rats; 100 to 352 mg/kg in mice; and 50 mg/kg in guinea pigs (NICNAS, 1994).

The dermal LD_{50} values are: 640 to 2,000 mg/kg in rabbits; > 2,500 mg/kg in rats; and > 4,500 mg/kg in mice (NICNAS, 1994).

The 4-hour inhalation LC_{50} values for glutaraldehyde are listed in Table 4:

Table 4: Acute inhalation LC_{50} values for Glutaraldehyde

Test Material	LC_{50} (males) [mg/L]	LC_{50} (females) [mg/L]	LC_{50} (both sexes) [mg/L]	Reference
50% aq. aerosol	0.52	0.45	-	OECD, 1995
25% aq. aerosol	-	-	0.8	OECD, 1995
50% aq. aerosol	0.35	0.28	-	OECD, 1995
5% soln. vapour	0.096	0.164	-	OECD, 1995

During the exposure period, the animals showed signs of eye and respiratory irritation, as indicated by laboured and audible breathing, and wetness and encrustation around the nose and eyes.

D. Irritation

Glutaraldehyde is corrosive to the skin and eyes of rabbits (NICNAS, 1994; ECHA). Signs of irritation occurred at a concentration of 2% for skin and 0.2% for eyes (NICNAS, 1994). In the acute inhalation studies, rats exposed to aerosols or vapours of glutaraldehyde showed signs of eye and respiratory irritation (OECD, 1995).

E. Sensitisation

Glutaraldehyde is a skin sensitiser to guinea pigs and humans. Information on the individual studies can be found in NICNAS (1994) and in the ECHA REACH database (ECHA).

Asthmatic symptoms, such as wheezing, coughing, chest tightness, breathing difficulties and non-specific hyper-responsiveness have been reported to occur in humans occupationally exposed to glutaraldehyde (NICNAS, 1994). It is unclear whether the asthma is an allergic hypersensitivity response or a result of the aggravation of pre-existing asthma due to the irritating properties of

glutaraldehyde. Nevertheless, glutaraldehyde should be considered a respiratory sensitiser, although one of low potency.

F. Repeated Dose Toxicity

Oral

Male and female Wistar rats were given in their drinking water 0, 100, 500, or 2,000 ppm glutaraldehyde for 90 days. The approximate daily intakes were 0, 3, 15 or 53 mg/kg/day for males, and 0, 4, 19 or 72 mg/kg/day for females. There were no signs of neurotoxicity at any dose level. There was slight impairment of food consumption in the 2,000 ppm animals, as well as slight impairment of body weight and body weight gain. Impaired water consumption was seen in the 100 and 500 ppm females. The NOAEL for males is 500 ppm (15 mg/kg/day). The NOAEL for females is 100 ppm (4 mg/kg/day) since the impaired water consumption in the 100 ppm females was considered a palatability problem and not an adverse effect (ECHA) [Kl. score = 1].

Male and female F344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 13 weeks. Additional groups of animals were given in their drinking water 0 or 1,000 ppm glutaraldehyde for 13 weeks followed by a 4-week recovery period. The approximate daily intakes were 0, 5, 25 or 100 mg/kg/day for males; and 0, 7, 35 or 120 mg/kg/day for females. Water consumption was reduced in a dose-dependent manner in the $\geq$ 250 ppm males and 1,000 ppm females, which was attributed to an aversion to the taste and/or odour of glutaraldehyde in the water. There was also a reduction in food consumption in the 1,000 ppm animals with a parallel reduction in body weights. It is unclear whether the reduction in food consumption was related to the decreased water consumption. Urine volume was decreased with an increase in specific gravity, along with a slight increase in protein and ketone concentration, in the $\geq$ 250 ppm animals, which was probably related to the decreased water consumption. There were no treatment-related changes in the haematology parameters measured. Blood urea nitrogen was increased in a dose-related manner in the $\geq$ 250 ppm females at the 6-week time point, but not at the 13-week or 17-week time points. Relative kidney weights were increased in a dose-related manner in the $\geq$ 250 ppm males and females and increased absolute kidney weights in the females. Histopathological examination showed no treatment-related effects. The NOAEL is 50 ppm (5 and 7 mg/kg/day for males and females, respectively) based on dose-related increase in kidney weights at $\geq$ 250 ppm (ECHA) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for 12 months. The approximate daily intakes were: 0, 6.4, 30.5, or 116.6 mg/kg/day for males; and 0. 9.6, 46, or 153 mg/kg/day for females. There was no treatment-related mortality. At 2,000 ppm, treatment-related effects included respiratory sounds (both sexes), decrease in body weight (males), decrease in body weight gain (both sexes), decrease in food consumption (both sexes), reduced water consumption (both sexes), lesions within the glandular stomach (both sexes showed erosion/ulceration of the glandular stomach), increased incidence of clear cell foci in the liver (males) and a single case of slight diffuse squamous metaplasia in the epithelium of the larynx (male). At 500 ppm, water consumption was reduced in males which was considered to be a palatability (bad taste) problem and not an adverse effect. No effects were seen in the 100 ppm animals. The NOAEL for this study is 500 ppm, which corresponds to 30.5 and 46 mg/kg/day for males and females, respectively (ECHA) [Kl. score = 1].

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. There were no treatment-related mortalities or clinical symptoms of toxicity. In the 250 and 1,000 ppm groups, there was reduction in

body weight and body weight gain; reduction in food and water consumption; increased statistically significant incidence of nucleated erythrocytes and of large monocytes; decreases in alanine aminotransferase (ALT), aspartate aminotransferase (AST), and glutamate dehydrogenase; dose-related decrease in urine volume accompanied by a dose-related increase in osmolality; changes in absolute and relative kidney weight; gastric irritation; increases in bone marrow hyperplasia; and increased incidence of renal tubular pigmentation. The decreased water consumption was considered to be due to the bad taste, smell and/or irritancy of the test substance in the drinking water; thus, it is of no toxicological relevance. As a result of reduced water intake, there are renal physiological adaptation, such as decreased urine, increased osmolality and changes in kidney weight. The haematological and clinical chemistry parameter changes were marginal and were considered to be of no toxicological relevance. The main haematological finding seen at the end of the study, which consisted of the appearance of nucleated erythrocytes and large monocytes in all treated groups (statistically significant for the ≥250 ppm males), was related to the incidence of large granular lymphocytic leukaemia (LGLL) in the spleen. The bone marrow hyperplasia and renal tubular pigmentation are related to the occurrence/incidence of LGLL and were considered by the authors of the study as being secondary to low-grade haemolytic anaemia in animals with LGLL. The NOAEL for this study is 50 ppm which corresponds to 4 and 6 mg/kg/day for males and females, respectively (Van Miller et al., 2002) [Kl. score = 2].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathological lesions in the nasal passages and turbinates were seen at ≥ 0.25 ppm. Treatment-related effects were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing concentration of glutaraldehyde. The NOAEL for this study is 0.125 ppm (Gross et al., 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125, 0.25, 0.5 or 1.0 ppm (0, 0.26, 0.5, 1, 2 or 4.1 mg/m^3) glutaraldehyde for 6.5 hours/day, 5 days/week for 13 weeks. The study focused on the respiratory tract, using histopathology and epithelial cell labelling index as end points. Histopathologic lesions in the nasal passages and turbinates were seen at all exposure concentrations (≥ 0.0625 ppm). Treatment-related lesions were primarily the respiratory mucosa (nasal cavity and tips of the turbinates) and the olfactory epithelium (dorsal meatus). Hyperplasia, squamous metaplasia, olfactory degeneration, squamous exfoliation (accumulation of keratin, cell debris and bacteria in the lumen of the nasal vestibule) and focal erosions were reported for both sexes, and the severity and incidence of the findings increased with increasing test concentration. Furthermore, neutrophilic inflammation was seen at ≥ 0.062 ppm, and squamous metaplasia as well as necrosis were seen in the larynx at 1 ppm. The LOAEL for this study is 0.0625 ppm; a NOAEL was not established (Gross et al*.,* 1994) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.41 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. Survival was similar between treated and control groups. Hyperplasia of the squamous epithelium lining of the dorsal wall of the nasal passages and the lateral aspect of the atrioturbinate was seen in a greater number of exposed females than in controls. Epidermal erosion and ulceration as well as squamous and inflammatory exfoliation were also seen in the nasal lumens. All of these changes were dependent on the length of

glutaraldehyde exposure. The authors concluded that, since the induced lesions occurred in the more anterior part of the nasal passages, that they were likely the result of an irritation mechanism (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5, or 0.75 ppm (0, 1, 2, or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Mean body weights of all exposed males and the mid- and high-dose females were generally less than those of the controls. Non-neoplastic lesions were limited primarily to the most anterior region of the nasal cavity. Effects included hyperplasia and inflammation of the squamous epithelium; hyperplasia, goblet cell hyperplasia, inflammation and squamous metaplasia of the respiratory epithelium; and hyaline degeneration of the olfactory epithelium. The LOAEL for this study is 0.25 ppm based on hyperplasia and inflammation of the squamous epithelium of the nose in both sexes. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. Mean body weights of the high-dose females were generally lower than the controls. Non-neoplastic lesions were limited primarily to the anterior region of the nasal cavity; the effects were qualitatively similar to those seen in the rats (see accompanying summary on the two-year rat study by van Birgelen et al. [2000]). Squamous metaplasia of the respiratory epithelium was observed in both sexes of mice while female mice also had inflammation and hyaline degeneration of the respiratory epithelium. The incidence and severity grade (in parentheses) of the hyaline degeneration were: 16/50 (1.4), 35/49 (1.4), 32/50 (1.3) and 30/50 (1.1) for the 0, 0.0625, 0.125 and 0.25 ppm dose groups, respectively. The LOAEL for this study is 0.0625 ppm based on hyaline degeneration of the respiratory epithelium in female mice. A NOAEL was not established (van Birgelen et al., 2000) [Kl. score = 2].

Dermal

Applications of a 50% solution of glutaraldehyde was applied to the skin of male and female SD rats for 13 weeks. The doses were 0, 50, 100 and 150 mg/kg glutaraldehyde. At the application site, there were signs of irritation (scabs, desquamation and very slight or well-defined erythema). There was no treatment-related mortality, clinical signs, body weights, feed consumption and ophthalmoscopic effects. There were no changes in the haematology and clinical chemistry parameters that were considered to be biologically or toxicologically relevant. Organ weights were similar between treated and control animals. Histopathological examination showed treatment-related effects in the skin associated with chronic irritation; no other changes were noted that were considered to be treatment-related. The NOAEL for this study is 150 mg/kg, the highest dose tested (ECHA) [Kl. score = 1].

G. Genotoxicity

In Vitro Studies

Glutaraldehyde may exhibit weak genotoxic effects in some *in vitro* tests. The bacterial reverse mutation assays have been the most consistent. Variable results have been reported for the forward gene mutation tests; and for sister chromatid exchange (SCE), chromosomal aberration and Unscheduled DNA Synthesis (UDS) tests (Vergnes and Ballantyne, 2002).

In Vivo Studies

The *in vivo* studies conducted on glutaraldehyde are presented in Table 5. All the studies show that glutaraldehyde is not mutagenic or genotoxic.

Table 5: *In Vivo* Genotoxicity Studies on Glutaraldehyde

Test System	Results*	Klimisch Score	Reference
Rat bone marrow (chromosomal aberration)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Mouse bone marrow (micronucleus)	-	1	ECHA
Rat bone marrow (chromosomal aberration)	-	2	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Drosophila SLRL Test	-	2	ECHA
Rat liver UDS Assay	-	1	ECHA
Rat germ cell cytogenetic assay (alkaline elution)	-	2	ECHA
Mouse peripheral blood micronucleus study	-	2	Vernes and Ballantyne (2002)
Rat liver UDS Assay	-	2	Mirsalis *et al.* (1989)

* +, positive; -, negative

H. Carcinogenicity

Oral

Male and female Fischer 344 rats were given in their drinking water 0, 50, 250 or 1,000 ppm glutaraldehyde for 104 weeks. The mean glutaraldehyde consumption was 0, 4, 17 and 64 mg/kg/day for males and 0, 6, 25 and 86 mg/kg/day for females. Mortality rates were 25-30% and 19-23% for males and females, respectively, with no dose-related increase. The major cause of death in all dose groups including the controls was LGLL. There was an increased incidence of LGLL in the liver and spleen in all treated females ($\geq$ 50 ppm). The incidence of LGLL was not significantly increased in the treated males compared to the controls. No other treatment-related increased incidence of tumours was seen (Van Miller et al., 2002) [Kl. score = 2].

Male and female Wistar rats were given in their drinking water 0, 100, 500 or 2,000 ppm glutaraldehyde for two years. The mean daily intake of glutaraldehyde was as follows: 0, 6.1, 31.9 and 120.7 mg/kg/day for males; and 0, 10.5, 48.5 and 176.4 mg/kg/day for females. In the high-dose animals, there was mortality (2 males and 9 females) from asphyxia, and mean terminal body weights were significantly decreased compared to the controls. There were no treatment-related neoplastic effects (ECHA) [Kl. score = 1].

Inhalation

Male and female $B6C3F_1$ mice were exposed by inhalation to 0 or 0.1 ppm (0 or 0.4 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for 52 and 78 weeks. No exposure-related neoplastic lesions were observed in either males or females (Zissu et al., 1998) [Kl. score = 2].

Male and female Fischer 344 rats were exposed by inhalation to 0, 0.25, 0.5 or 0.75 ppm (0, 1, 2 or 3.1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival in the mid- and high-dose females was statistically significantly decreased compared to controls. Survival of the treated males was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 0.0625, 0.125 or 0.25 ppm (0, 0.26, 0.5 or 1 mg/m^3) glutaraldehyde for 6 hours/day, 5 days/week for two years. Survival of the treated animals was similar to controls. No exposure-related neoplastic lesions were observed in either males or females (van Birgelen et al., 2000) [Kl. score = 2].

I. Reproductive Toxicity

A two-generation reproductive toxicity study was conducted in Wistar rats given 0, 100, 500 and 2,000 ppm glutaraldehyde in their drinking water. The approximately mean daily intake is 0, 12, 58 and 199 mg/kg/day for the parental males and females of the F_0 and F_1 generation during premating. There were no adverse effects on reproductive performance or fertility. Oestrous cycle data, mating behaviour, conception, gestation, parturition, lactation and weaning as well as sperm parameters, sexual organ weights, gross and histopathological findings of these organs were similar between treated and control groups. In the high-dose animals, there was decreased water and/or food consumption; and decreased body weights and/or reduced body weight gains during the premating periods in the F_0 and F_1 parental females during premating, gestation and/or lactation. The high-dose F_1 parental females also had increased the number of erosions/ulcers with microscopic erosion(s) or inflammatory oedema in the mucosa/submucosa of the glandular stomach. There were no adverse effects in the 500 ppm animals except for slight decreases in water consumption due to a palatability (bad taste) problem. Treatment-related signs of developmental toxicity were seen in the progeny of the high-dose F_0 and F_1 parental generation and included impairment in body weight and consequently in organ weights in the respective F_1 and F_2 pups. The NOAEL for reproductive toxicity is 2,000 ppm (199 mg/kg/day), the highest dose tested. The NOAEL for parental systemic toxicity is 500 ppm (58 mg/kg/day). The NOAEL for developmental toxicity is 500 ppm or 58 mg/kg/day (ECHA) [Kl. score = 1].

A two-generation reproductive toxicity study was conducted in Crj: CD(SD) rats given 0, 50, 250 and 1,000 ppm glutaraldehyde in their drinking water. Mean daily intake was not calculated. Parental body weights and body weight gains were significantly reduced at 1,000 ppm at some periods, particularly during pre-mating. Food consumption was significantly reduced at 1,000 ppm for the F_0 and F_1 parental animals during pre-mating and gestation, and F_1 females during lactation. Water consumption was reduced throughout the pre-mating period for the F_0 and F_1 250 and 1,000 ppm parental animals. There was no indication of adverse effects on reproductive performance or fertility at any dose level. For the F_1 1,000 ppm offspring, body weights were reduced from lactation days 21-28. The NOAEL for reproductive toxicity is 1,000 ppm, the highest dose tested. The NOAEL for parental systemic toxicity is 50 ppm. The NOAEL for developmental toxicity is 250 ppm (Neeper-Bradley and Ballantyne, 2000) [Kl. score = 2].

J. Developmental Toxicity

Pregnant Wistar rats were given in their drinking water 0, 50, 250 or 750 ppm (0, 5, 26 or 68 mg/kg) glutaraldehyde from GD 6 to 16. Water consumption was reduced in a dose-related manner in the $\geq$ 250 ppm dams, and was considered not to be a toxic response, but due to the palatability (bad taste) of the drinking test solution. No other maternal effects were seen in the study. There were no significant differences between treated and controls in the sex distribution, placental weights, foetal

weights, malformations or variations. The NOAEL for maternal and developmental toxicity in this study is 68 mg/kg/day, respectively (ECHA) [Kl. score = 1].

Pregnant Wistar rats were dosed by oral gavage with 0, 25, 50 or 100 mg/kg glutaraldehyde on GD 6 to 15. Mortality was significantly increased in the high-dose group (5/26); there were 2/21 deaths in the mid-dose group. Clinical signs (piloerection) occurred in all treated groups in a dose-dependent manner. Maternal body weight gain and feed consumption were significantly reduced in the high-dose dams, but not at the lower doses. The necropsy findings showed evidence of stomach irritation in almost all of the animals that died during the study and in 12/21 of the surviving dams in the high-dose group. The number of implantations per litter, resorptions and dead foetuses per litter, live foetuses per litter and incidence of post-implantation loss per litter was similar across all groups. The mean foetal body weights for male and female foetuses were significantly reduced in the high-dose group; this was attributed to the reduced food consumption of the dams during gestation rather than a direct effect of treatment. There was no evidence of a treatment-related teratogenic effect. The NOAEL for maternal and developmental toxicity is 50 mg/kg/day, respectively (Ema et al., 1992) [Kl. score = 2].

Pregnant Himalayan rabbits were dosed by oral gavage with 0, 5, 15 or 45 mg/kg glutaraldehyde on GD 7 to 19. In the high-dose group, 5/15 died on GD 9-11. Food consumption and body weight gain were also significantly reduced in the high-dose group. Clinical observations in 12/15 high-dose does included soft faces, diarrhoea and blood in the bedding. The mean gravid uterus weight was significantly reduced in the high-dose group. Post-implantation loss was greatly increased (94.3%) in the high-dose group: no viable foetuses in 9/15 of the high-dose does, only early resorptions; only one female gave four alive foetuses on the scheduled date. There were reduced placental and foetal body weights in the only four foetuses. No significant maternal or developmental effects were seen in the mid- and low-dose groups. The NOAEL for maternal and developmental toxicity in this study is 15 mg/kg/day (ECHA) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for glutaraldehyde follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2011).

A. Non-Cancer

The lowest NOAEL values from key toxicity studies on glutaraldehyde are listed in Table 6.

Table 6: Lowest NOAEL Values from Key Toxicity Studies on Glutaraldehyde by the Oral Route

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, female	90/days	4	Decreased body weights, food and water consumption	ECHA
Rats, male	13-wk (drinking water)	5	Increased kidney weights	ECHA

Species/Sex	Study Duration	mg/kg/day	Endpoint	Reference
Rats, male	12-months (drinking water)	30.5	Clinical signs; decreased body weights and food consumption; increased clear cell foci in liver	ECHA
Rats, male	2-yr (drinking water)	4	Reduced body weight, body-weight gain, and food consumption	Van Miller *et al.* (2002)
Rats	2-generation (drinking water)	58	Systemic toxicity	ECHA
Rats	GD 6-16 (drinking water)	68	Developmental toxicity	ECHA
Rats	GD 6-15 (oral gavage)	50	Developmental toxicity	Ema *et al.* (1992)
Rabbits	GD 7-19 (oral gavage)	15	Developmental toxicity	ECHA

The lowest NOAEL from these studies is 4 mg/kg/day based on reduced body weights, body weight gain and feed consumption in male rats from the two-year drinking water study (Van Miller et al., 2002). The NOAEL of 4 mg/kg/day will be used for determining the oral Reference Dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4/(10 x 10 x 1 x 1 x 1) = 4/100 = <u>0.04 mg/kg/day</u>

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD: Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2011)
Proportion of water consumed = 10% (ADWG, 2011)
Volume of water consumed = 2 L (ADWG, 2011)
Drinking water guidance value = (0.04 x 70 x 0.1)/2 = 0.14 mg/L

B. Cancer

Increased incidence of large granular cell lymphatic leukaemia (LGLL) was observed in all groups of male and female Fischer 344 rats given glutaraldehyde in their drinking water, including the controls (Van Miller *et al.,* 2002). For the males, the incidence of LGLL was not statistically significantly increased. However, for the females, the incidence of LGLL was significantly increased in all treated females (≥ 50 ppm). Inhalation exposure of Fischer 344 rats to glutaraldehyde did not result in an increased incidence of tumours, including LGLL.

LGLL, also known as mononuclear cell leukaemia, is an extremely common spontaneous neoplastic disease of the ageing F344 rat (Stromberg, 1985; Ward *et al.* 1990; Thomas et al., 2007). Consistent features are splenomegaly, anaemia, thrombocytopenia and leukemic infiltration of the spleen, liver, lung, and in an advanced stage, of several other organs. The incidence is variable but has been increasing progressively with time and can exceed 70% in controls in some studies. This compares with background incidence of less than 1% in other strains of commonly used laboratory rats (Haseman et al., 1998; Thomas et al., 2007). The incidence in F344 rats is modulated by a variety of factors not clearly related to carcinogenicity. Corn oil gavage, for example, has been shown consistently to reduce the incidence of MCL in male, but not female, controls (reviewed in Thomas et al., 2007).

The neoplastic mononuclear cells appear to be derived from large granular lymphocytes (LULs) (reviewed in Thomas et al., 2007). The tumour cell is of the NK type in most, if not all, cases. LGL leukaemia, although uncommon, does occur in humans. There are two types: T-LGL leukaemia which has a chronic course characterised by neutropenia, recurrent infections, splenomegaly and accompanying rheumatoid arthritis, and the much rarer NK-LGL leukaemia which has an acute course, more pronounced splenomegaly, and thrombocytopenia. The latter type appears to resemble more closely the disease in the F344 rat than the former. The aetiology of human LGL leukaemia is unknown. There is some evidence that viral infection may play a role but no evidence that a chemically-related increased of LGLL in the F344 rat is indicative of the potential to induce LGL leukaemia in humans.

To extrapolate results from an animal model that has a clear predisposition (high spontaneous rates) to a tumour type to humans, of which this is not the case, seems inappropriate if the mechanism(s) for LGLL formation in that strain is not understood. Although that rat strain may be useful for understanding the disease process in humans, it does not seem reasonable to use the results from that rat strain for risk assessment purposes. There should be confirmation of a putative leukemogenic effect in the F344 rat in another strain before any conclusions are made about the use of this tumour type for human health risk assessment purposes.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Glutaraldehyde does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Glutaraldehyde has a moderate acute toxicity concern to fish and invertebrates, but is highly toxic to algae. It is of low toxicity concern to terrestrial invertebrates and plants. To birds, glutaraldehyde is moderately toxic on an acute basis and slightly toxic on a subacute dietary basis.

B. Aquatic Toxicity

Acute Studies

Table 7 lists the results of acute aquatic toxicity studies conducted on glutaraldehyde.

Table 7: Acute Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill sunfish	96-hr LC_{50}	13	2	ECHA
Oncorhynchus mykiss	96-hr LC_{50}	10	2	ECHA
Daphnia magna	48-hr LC_{50}	14.87	2	ECHA
Daphnia magna	48-hr LC_{50}	14	2	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.375 (biomass) 0.6 (growth rate) 0.025 (NOEC)	1	ECHA
Scenedesmus subspicatus	72-hr EC_{50}	0.92 (growth rate) 0.61(biomass) 0.33 (NOEC)	2	ECHA; Leung, 2001
Scenedesmus subspicatus	72-hr EC_{50}	0.61 (growth rate)	2	ECHA

Chronic Studies

The chronic aquatic toxicity studies conducted on glutaraldehyde are listed in Table 8.

Table 8: Chronic Aquatic Toxicity Studies on Glutaraldehyde

Test Species	Endpoint	Results (mg/L)	Kl. score	Reference
Oncorhynchus mykiss	97/day (OECD 210)	LOEC = 5 NOEC = 1.6	1	ECHA
Daphnia magna	21/day	NOEC = 5	1	ECHA

C. Terrestrial Toxicity

Table 9 lists the results of toxicity studies conducted on glutaraldehyde with earthworms, soil microorganisms and birds.

Table 9: Terrestrial Toxicity Studies on Glutaraldehyde

Test Species (method)	Endpoint	Results	Kl. score	Reference
Earthworm *Eisenia fetida* (OECD 207)	14-d LC_{50}	> 500 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 216)	28-d EC_{50} 28-d EC_{10}	360 mg/kg soil dw 11.5 mg/kg soil dw	1	ECHA
Soil microorganisms* (OECD 217)	28-d EC_{50} 28-d EC_{10}	> 593 mg/kg soil dw 1.5 mg/kg soil dw	1	ECHA
Mallard ducks	Single-dose (oral gavage) LC_{50}	206 mg/kg	2	ECHA
Mallard ducks	5-d (dietary) NOEC	> 2,500 ppm	1	ECHA

*organic carbon content of soil = 1.34% dry weight

Glutaraldehyde has also been evaluated in a terrestrial plants test: seedling emergence and seedling growth test (OECD TG 208). The test material contained 48.9% glutaraldehyde. The results are as follows:

Avena sativa (oats): 19/day EC_{50} value is > 1,000 mg/kg soil dry weight based on emergence rate, dry weight and shoot length. The NOECs for *Avena sativa* (oats) were $\geq$ 1,000 mg/kg dry weight on all three parameters tested.

Brassica napus (rapeseed): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length and 994 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 500 and 250 mg/kg soil dry weight for emergence rate, dry matter and shoot length, respectively.

Vicia sativa (vetch): 19/day EC_{50} is > 1,000 mg/kg soil dry weight based on emergence rate and shoot length, and 901 mg/kg soil dry weight based on dry weight. The NOECs were $\geq$ 1,000, 125 and 125 mg/kg soil dry weight for emergence rate, dry matter, and shoot length, respectively (ECHA) [Kl. score = 1].

D. Calculation of PNEC

The PNEC calculations for glutaraldehyde follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (10 mg/L), *Daphnia* (14 mg/L) and algae (0.375 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 0.025 mg/L for algae. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 0.025 mg/L for algae. The $PNEC_{water}$ is 0.0025 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.006 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (3.1/1280) \times 1000 \times 0.0025$
$= 0.006$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [(0.2 \times 4.8)/1000 \times 2400]$
$= 3.1\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{0c} \times f_{oc}$
$= 120 \times 0.04$
$= 4.8$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for glutaraldehyde in sediment is 120.
F_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil

Experimental results are available for three trophic level. An acute LC_{50} value is available for earthworms (> 500 mg/kg). Results from long-term studies are available for two trophic levels, with the lowest NOEC or EC_{10} being 1.5 mg/kg soil dry weight for soil organisms.

The EC_{10} value is corrected for bioavailability of glutaraldehyde in soil by normalising to the fraction organic carbon matter content (Fom) in the soil using the following equation:

$EC_{10(std)} = EC_{10(exp)} \times Fom_{soil(std)}/Fom_{soil(exp)}$

Where:
$Fom_{soil(std)}$ = 1% (default soil fraction organic matter)
$Fom_{soil(exp)}$ = 1.34% (see Table 9)
$EC_{10(std)}$ = 1.5 mg/kg x 1/1.34 = 1.12 mg/kg

On the basis that the data consists of one short-term result from one trophic level and two long-term results from two additional levels, an assessment factor of 50 has been applied to the lowest reported long-term EC_{10} of 1.12 mg/kg soil dry weight [corrected for organic carbon content] for soil organisms. The $PNEC_{soil}$ is 0.02 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Glutaraldehyde is readily biodegradable and thus does not meet the screening criteria for persistence.

The log K_{ow} for glutaraldehyde at different pH values ranges from -0.36 to -0.80. Thus, glutaraldehyde does not meet the screening criteria for bioaccumulation.

The lowest NOEC value from chronic aquatic toxicity studies is < 0.1 mg/L. Thus, glutaraldehyde meets the screening criteria for toxicity.

The overall conclusion is that glutaraldehyde is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 3 [oral]

Acute Toxicity Category 2 [inhalation]

Skin Corrosion Category 1B

Eye Damage Category 1

Respiratory Sensitiser 1A

Skin Sensitiser 1A

STOT Single Exposure Category 3 [respiratory irritation]

Aquatic Acute Category 1

Aquatic Chronic Category 2

The appropriate hazard statements corresponding the GHS classifications are to be added to the SDS, including the non-GHS hazard statement “AUH071: Corrosive to the Respiratory Tract”.

B. Labelling

Danger

C. Pictograms



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

First aid information was obtained from the ECHA REACH database (ECHA).

Eye Contact

Wash immediately and continuously with flowing water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Obtain prompt medical consultation, preferably from an ophthalmologist. Eye wash fountain should be located in immediate work area.

Skin Contact

Take off contaminated clothing. Wash skin with soap and plenty of water for 15-20 minutes. Call a poison control centre or doctor for treatment advice. Wash clothing before reuse. Shoes and other leather items which cannot be decontaminated should be disposed of properly. Safety shower should be located in immediate work area.

Inhalation

Move person to fresh air. If a person is not breathing, call an emergency responder or ambulance, then give artificial respiration; if by mouth-to-mouth use rescuer protection (pocket mask, etc.). Call a poison control centre or doctor for treatment advice. If breathing is difficult, oxygen should be administered by qualified personnel.

Ingestion

If the person is fully alert and cooperative, have the person rinse mouth with plenty of water. In cases of ingestion have the person drink 4 to 10 ounces (120-300 mL) of water. Do not induce vomiting. Do not attempt mouth rinse if the person has respiratory distress, altered mental status, or nausea and vomiting. Call a physician and/or transport to an emergency facility immediately. See Note to Physician. Seek medical attention immediately.

Notes to Physician

Maintain adequate ventilation and oxygenation of the patient. May cause asthma-like (reactive airways) symptoms. Bronchodilators, expectorants, antitussives and corticosteroids may be of help. Glutaraldehyde may transiently worsen reversible airways obstruction including asthma or reactive airways disease. Chemical eye burns may require extended irrigation. Obtain prompt consultation, preferably from an ophthalmologist. If the burn is present, treat as any thermal burn, after decontamination. Due to irritant properties, swallowing may result in burns/ulceration of mouth,

stomach and lower gastrointestinal tract with subsequent stricture. Aspiration of vomitus may cause lung injury. Suggest endotracheal/oesophagal control if lavage is done. Probable mucosal damage may contraindicate the use of gastric lavage. Inhalation of vapours may result in skin sensitisation. In sensitised individuals, re-exposure to very small amounts of vapour, mist or liquid may cause a severe allergic skin reaction. No specific antidote. Treatment of exposure should be directed at the control of symptoms and the clinical condition of the patient. Have the Safety Data Sheet, and if available, the product container or label with you when calling a poison control centre or doctor, or going for treatment.

Medical Conditions Aggravated by Exposure

Excessive exposure may aggravate pre-existing asthma and other respiratory disorders (e.g., emphysema, bronchitis, reactive airways dysfunction syndrome).

Emergency Personnel Protection

First Aid responders should pay attention to self-protection and use the recommended protective clothing (chemical resistant gloves, splash protection). If the potential for exposure exists, refer to Section 8 of the Safety Data Sheet for specific personal protective equipment.

B. Fire Fighting Information

Firefighting information was obtained from the ECHA REACH database (ECHA).

Extinguishing Media

Use water fog, carbon dioxide, dry chemical or foam to extinguish combustible residues of this product

Specific Exposure Hazards

This material will not burn until the water has evaporated. Residue can burn. Some components of this product may decompose under fire conditions. The smoke may contain unidentified toxic and/or irritating compounds. Combustion products may include, and are not limited to, carbon monoxide and carbon dioxide.

Special Protective Equipment for Firefighters

Wear positive-pressure self-contained breathing apparatus (SCBA) and protective firefighting clothing (includes firefighting helmet, coat, trousers, boots and gloves). Avoid contact with this material during firefighting operations. If contact is likely, change to full chemical resistant firefighting clothing with self-contained breathing apparatus. If this is not available, wear full chemical resistant clothing with self-contained breathing apparatus and fight the fire from a remote location.

C. Accidental Release Measures

Information on accidental release measures was obtained from the ECHA REACH database (ECHA).

Personal Precautions

Use appropriate safety equipment. Evacuate area. Keep upwind of the spill. Ventilate area of leak or spill. Only trained and properly protected personnel must be involved in clean-up operations.

Environmental Precautions

Spills or discharge to natural waterways is likely to kill aquatic organisms. Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.

Steps to be Taken if Material is Released or Spilt

Avoid making contact with spilt material; glutaraldehyde will be absorbed by most shoes. Always wear the correct protective equipment, consisting of splash-proof mono-goggles, or both safety glasses with side shields and a wraparound full-face shield, appropriate gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilt material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilt material with water to reduce odour, and discharge the rinsate into a municipal or industrial sewer.

Large spills: In the case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious to glutaraldehyde, including rubber boots or shoe protection. Deactivate with sodium bisulphite (2-3 parts [by weight] per part of active substance glutaraldehyde), collect the neutralised liquid and place in a drum for transit to an approved disposal site.

D. Storage and Handling

Information on storage and handling was obtained from the ECHA REACH database (ECHA).

General Handling

Do not get in eyes, on skin, on clothing. Avoid breathing vapour. Do not swallow. Keep container closed. Use with adequate ventilation. Wear goggles, protective clothing and butyl or nitrile gloves. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

Other Handling Precautions

Do not spray or aerosolise the undiluted form of the product. Full personal protective equipment (including skin covering and full-face SCBA respirator) is required for dilutions or mixtures of the product used in a spray application.

Storage

Do not store in: Aluminium. Carbon steel. Copper. Mild steel. Iron. Shelf life: Use within 12 Months.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for glutaraldehyde in Australia is 0.1 ppm (0.41 mg/m^3) as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

The information below on exposure controls and personal protection was obtained from the Halliburton Safety Data Sheet (SDS) on ALDACIDE® G ANTIMICROBIAL (revision date: 11-Dec-2014).

Engineering Controls

Use in a well-ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation. If vapours are strong enough to be irritating to the nose or eyes, the TLV is probably being exceeded, and special ventilation or respiratory protection may be required.

Personal Protection Equipment

Respiratory Protection: If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH-certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Full Facepiece Respirator with Organic vapour cartridge with particulate pre-filter.

Hand Protection: Chemical-resistant protective gloves (EN 374). Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480-minute permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness). This information is based on literature references and on information provided by glove manufacturers or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g., temperature). If signs of wear and tear are noticed, then the gloves should be replaced. Manufacturer's directions for use should be observed because of the great diversity of types.

Skin Protection: Butyl coated apron or clothing.

Eye protection: Splash proof chemical mono-goggles or safety glasses with side shield in conjunction with a face shield. Do NOT wear contact lenses.

Other Precautions: Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

For aqueous glutaraldehyde solutions at a concentration that is corrosive (i.e., 30% and higher):

Australia Dangerous Goods

UN3265, Corrosive Liquid, Acidic, Organic, N.O.S. (Contains Glutaraldehyde)

Class 8

Packing Group III

Environmentally Hazardous Substance

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state, and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII.REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ema, M., Itami, T., and Kawasaki, H. (1992). Teratological assessment of glutaraldehyde in rats by gastric intubation. Toxicol. Lett. 63: 147-153.

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Frantz, S.W., Beskitt, J.L., Tallant, M.J., Futrell, J.W., and Ballantyne, B. (1993). Glutaraldehyde: species comparisons of in vitro skin penetrations. J. Toxicol.-Cut. & Ocular Toxicol. 12: 349-361.

Gross, E.A., Mellick, P.W., Kari, F.W., Miller, F.J., and Morgan, K.T. (1994). Histopathology and cell replication responses in the respiratory tract of rats and mice exposed by inhalation to glutaraldehyde for up to 13 weeks. Fundam. Appl. Toxicol. 23: 348-362.

Haseman, J.K., Hailey, J.R., and Morris, R.W. (1998). Spontaneous neoplasm incidences in Fischer 344 rats and B6C3F_1 mice in two-year carcinogenicity studies: A National Toxicology Program update. Toxicol. Pathol. 26: 428-441.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Leung, H.W. (2001). Ecotoxicology of glutaraldehyde: review of environmental fate and effects studies. Ecotoxicol. Environ. Safety 49: 26-39.

Mirsalis, J.S., Tyson, C.K., Steinmetz, K.L., Loh, E.K., Hamilton, C.M., Bakke, J.P., and Spalding, J.W. (1989). Measurement of unscheduled DNA synthesis and S-phase synthesis in rodent hepatocytes following in vivo treatment: testing of 24 compounds. Environ. Mol. Mutagen. 14: 155-164.

Neeper-Bradley, T.L., and Ballantyne, B. (2000). Two-generation reproduction study by dosing with glutaraldehyde in the drinking water of CD rats. J. Toxicol. Environ. Health A 61: 107-129.

NICNAS. (1994). Glutaraldehyde – Full Public Report. National Industrial Chemicals Notification and Assessment Scheme (NICNAS), AGPS, Canberra, Australia.

OECD. (1995). OECD-SIDS document on Glutaraldehyde, CAS No. 111-30-8, UNEP Publications. Accessed at: http://webnet.oecd.org/hpv/ui/SIDS_Details.aspx?id=b13f2e48-0425-4a8a-b7b8-c04cfaab06e8

Stromberg, P.C. (1985). Large granular lymphocyte leukaemia in F344 rats: Model for human T lymphoma, a malignant histiocytosis and T-cell chronic lymphocytic leukaemia. Am. J. Pathol. 119: 517-519.

Thomas, J., Haseman, J.K., Goodman, J.I., Ward, J.M., Loughran, Jr., T.P., and Spencer, P.J. (2007). A review of large granular lymphocytic leukaemia in Fischer 344 rats as an intial step toward evaluating the implication of the endpoint to human cancer risk assessment. Toxicol. Sci. 99: 3-19.

van Birgelen, A.P.J.M., Chou, B.J., Renne, R.A., Grumbein, S.L., Roycroft, J.H., Hailey, J.R., and Bucher, J.R. (2000). Effects of glutaraldehyde in a 2-year inhalation study in rats and mice. Toxicol. Sci. 55: 195-205.

Van Miller, J.P., Hermansky, S.J., Losco, P.E., and Ballantyne, B. (2002). Chronic toxicity and oncogenicity study with glutaraldehyde dosed in the drinking water of Fischer 344 rats. Toxicol. 175: 177-189.

Vergnes, J.S., and Ballantyne, B. (2002). Genetic toxicology studies with glutaraldehyde. J. Appl. Toxicol. 22: 45-60.

Ward, J.M., Rehm, S., and Reynolds, C.W. (1990). Tumours of the haematopoietic system. In: Pathology of Tumours in Laboratory Animals, Vol. 1, Second Edition (Turusov, V.S., and Mohr, U., Eds.), pp. 625-657, International Agency for Research on Cancer, Lyon, France.

Zissu, D., Bonnet, P., and Binet, S. (1998). Histopathological study in B6C3F1 mice chronically exposed by inhalation to glutaraldehyde. Toxicol. Lett. 95: 131-139.

GUAR GUM

This dossier on guar gum (CAS RN 9000-30-0) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the chemistry database PubChem. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): disodium;[[[5-(6-aminopurin-9-yl)-3-hydroxyoxolan-2-yl]oxy-methoxyphosphoryl]oxy-oxidophosphoryl] hydrogen phosphate

CAS RN: 9000-30-0

Molecular weight: 535.15 g/mol; 200,000 to 300,000 daltons (Glickman, 1969)

Molecular formula: $C_{10}H_{14}N_5Na_2O_{12}P_3$

Synonyms: GU-052, guar flour, guaran, gum guar, slocose

SMILES:: COP(=O)(OC1C(CC(O1)N2C=NC3=C(N=CN=C32)N)O)OP(=O)([O-])OP(=O)(O)[O-].[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Guar Gum

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Off-white to yellowish-white powder	-	PubChem
Vapour Pressure	Negligible	-	PubChem
Water Solubility	< 1 g/L @ 20°C (insoluble)	-	PubChem

III. ENVIRONMENTAL FATE PROPERTIES

Guar gum is a carbohydrate polymer consisting of D-mannose and D-galactose sugars from the guar plant or cluster bean. As a high molecular weight polysaccharide polymer, guar gum is expected to have a negligible vapour pressure. If released to air, a negligible vapour pressure indicates guar gum will exist solely in the particulate phase in the atmosphere. Particulate-phase guar gum will be removed from the atmosphere by wet and dry deposition. If released to soil, guar gum is expected to have no mobility since it is a polymer that binds strongly with soil particles. Volatilisation from moist soil surfaces is not expected to be an important fate process based upon a negligible Henry's Law constant. Likewise, guar gum is not expected to volatilise from dry soil surfaces based upon its vapour pressure. If released into water, guar gum is expected to adsorb to suspended solids and sediment (PubChem). Half-life data was not available.

Guar gum is expected to readily undergo microbial biodegradation in the environment (on the basis that it is a polysaccharide and expected to be readily biodegradable), and the potential to bioaccumulate in organisms is considered to be low (DoEE, 2017 and USEPA, 2005).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Guar gum exhibits very low acute toxicity by the oral route. It is non-irritating to the skin and minimally irritating to the eyes. Repeated dose toxicity studies in rats showed minimal toxicity from exposure to guar gum in the diet. Guar gum is not genotoxic or carcinogenic. Oral exposure to guar gum did not affect fertility in rats; nor was there any indication of developmental toxicity in either rats or mice.

NICNAS has assessed Guar Gum in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[1]

B. Acute Toxicity

The oral LD_{50} in rats was reported to be 7,060 mg/kg (Graham *et al.*, 1981) [Kl. Score = 2].

C. Irritation

Guar gum is non-irritating to the skin and minimally irritating to the eyes (McCarty *et al.*, 1990). Nonetheless, ECHA warns that the substance may cause serious eye irritation.

D. Sensitisation

There were reports of workers sensitised to guar gum in a carpet-manufacturing plant. Immediate skin reactivity to guar gum was observed in 8 out of 162 employees, and 11 of 133 participants had serum IgE antibodies to guar gum. These findings are difficult to interpret since carbohydrates, such as guar gum, are generally not associated with allergenicity (Malo, 1990).

E. Repeated Dose Toxicity

Oral

Male and female Osborne-Mendel rats were given diets containing 0, 1, 2, 4, 7.5, or 15% guar gum for 91 days. The average daily intakes are: 0; 580; 1,187; 2,375; 4,561 and 10,301 mg/kg/day for males; and 0; 691; 1,362; 2,762; 5,770 and 13,433 mg/kg/day for females. There were no deaths during the study. Body weights were significantly decreased in the ≥1% females and the ≥7.5% males; biologically significant changes (>10%) were seen in the 7.5% females and the 15% males. Liver weights were decreased in the ≥1% dietary groups. Kidney weights were decreased in the ≥7.5% dietary groups and were borderline significant in the 4% group. The 15% group males had reduced bone marrow cellularity; although the level was within normal limits, several of the rats were at the lower end of the normal range.

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9000-30-0%2C+

The NOAEL for this study is 4% in the diet or 2,762 mg/kg/day based on reduced body weights in the female rats (Graham *et al.*, 1981) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0; 6,300; 12,500; 25,000; 50,000 or 100,000 ppm guar gum for 13 weeks. Mean body weights were decreased in the 100,000 ppm male rats and in the ≥50,000 ppm female mice. A dose-related decrease in feed consumption was observed for male and female rats; male and female mice were comparable or higher than that of controls. There were no compound-related clinical signs or histopathological effects. The NOAELs for this study are 50,000 and 25,000 ppm for rats and mice, respectively. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs corresponds to 2,500 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Male and female F344 rats and B6C3F_1 mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks. Mean body weights of the high-dose females were lower than those of the controls after week 20 for mice and week 40 for rats. No compound-related clinical signs or adverse effects on survival were observed. Feed consumption by dosed rats and mice of either sex was lower than that of controls. There were no non-neoplastic histopathological effects in either rats or mice that were treatment-related. The NOAEL for both rats and mice is 25,000 ppm. Using the fraction of body weight that rats and mice consume per day as food (0.05 and 0.13, respectively; USEPA), the NOAELs correspond to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice (NTP, 1982) [Kl. Score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

Guar gum was not mutagenic to *S. typhimurium* strains TA 97, TA 98, TA 100, TA 102, TA 104, TA 1535, TA 1537, and TA1538 in the presence or absence of metabolic activation (Zeiger *et al.*, 1992) [Kl. Score = 2].

In Vivo Studies

Guar gum was inactive in a rat bone marrow cytogenetic assay at doses up to 5,000 mg/kg (Johnson *et al.*, 2015) Kl. Score = 4].

In a rat dominant lethal mutation test, rats were dosed by oral gavage with either a single or multiple doses of up to 5,000 mg/kg guar gum. There was no indication of a mutagenic effect by guar gum (Lee *et al.*, 1983) [Kl. Score = 2].

G. Carcinogenicity

Male and female F344 rats were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. There were increased incidences of

adenomas of the pituitary in male rats and pheochromocytomas of the adrenal medulla in female rats that were statistically significant, but these differences were considered to be unrelated to guar gum administration. When pituitary adenomas or carcinomas and when pheochromocytomas or malignant pheochromocytomas were combined, the statistical differences disappeared. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for F344 rats (NTP, 1982) [Kl. Score = 2].

Male and female $B6C3F_1$ mice were given diets containing 0 ppm, 25,000 ppm or 50,000 ppm guar gum for 103 weeks in an NTP chronic bioassay. Hepatocellular carcinomas occurred in treated male mice at incidences that were significantly lower than that in controls. The combined incidence of male mice with either hepatocellular adenomas or carcinomas was also significantly lower in the high-dose group. NTP concluded that, under conditions of this bioassay, guar gum was not carcinogenic for $B6C3F_1$ mice (NTP, 1982) [Kl. Score = 2].

H. Reproductive Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intakes for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. Fertility was unaffected by treatment. There were slightly fewer corpora lutea and implantations in the 15% dietary group, but implantation efficiency was unaffected. The NOAEL for reproductive toxicity is 5,200 mg/kg/day (Collins *et al.*, 1987) [Kl. Score = 2].

I. Developmental Toxicity

Oral

Male and female Osborne-Mendel rats were fed diets containing 0, 1, 3, 4, 7.5, or 15% guar gum for 13 weeks before mating, during mating and throughout gestation. The daily intake for the female rats during gestation were 0; 700; 1,400; 2,700; 5,200 or 11,800 mg/kg/day. There were no deaths during the study. In the 15% group, the number of viable foetuses per litter were slightly reduced but was not statistically significantly different from controls. The authors indicated that the reduction may have been an effect of the decreased number of corpora lutea because the number of resorptions was unaffected in this treatment group. There was no treatment-related effect on foetal development or sex distribution, and there were no teratogenic effects (Collins *et al.*, 1987) [Kl. Score = 2].

Pregnant female rats were dosed by oral gavage with 0, 9, 42, 200 or 900 mg/kg guar gum on GD 6 to 15. There was no maternal or developmental toxicity at any dose level. The NOAEL for maternal and developmental toxicity is 900 mg/kg/day (FDRL, 1973) [Kl. Score = 2].

Pregnant female CD-1 mice were dosed by oral gavage with 0, 8, 37, 170, or 800 mg/kg guar gum on GD 6 to 15. A significant number of deaths (6 out of 29) occurred in the 800 mg/kg dose group. There were indications of maternal toxicity in the surviving high-dose dams. There was no developmental toxicity at any dose level. The NOAELs for maternal and developmental toxicity are 170 and 800 mg/kg/day, respectively (FDRL, 1973) [Kl. Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for guar gum follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

In a two-year NTP chronic bioassay, female rats and mice given 50,000 ppm guar gum in their feed had lower body weights. There were no treatment-related non-neoplastic lesions in either rats or mice. The NOAEL for this study is 25,000 ppm for rats and mice, which corresponds to 1,250 mg/kg/day for rats and 3,250 mg/kg/day for mice.

The NOAEL of 1,250 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 1,250/(10 x 10 x 1 x 1 x 1) = 1,250/100 = 13 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

- Human weight = 70 kg (ADWG, 2021)
- Proportion of water consumed = 10% (ADWG, 2021)
- Volume of water consumed = 2L (ADWG, 2021)
- Drinking water guidance value = (13 x 70 x 0.1)/2 = 46 mg/L

B. Cancer

Guar gum was not carcinogenic to rats or mice in two-year dietary studies. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Guar gum does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Guar gum is a polysaccharide polymer. It has low acute toxicity concern for fish but exhibits moderate acute toxicity to invertebrates (*Daphnia*).

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} for *Oncorhynchus mykiss* is 218 mg/L (Biesinger *et al.*, 1976) [Kl. Score = 2].

The 48-hour and 96-hour LC_{50} values for *Daphnia magna* are 42 mg/L and <6.2 mg/L, respectively (Biesinger *et al.*, 1976) [Kl. Score = 2].

Chronic Studies

No studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for guar gum follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. The acute LC_{50} values are available for fish (218 mg/L) and *Daphnia* (<6.2 mg/L). No chronic studies are available. On the basis that the data consists of acute studies from two trophic levels, an assessment factor of 1,000 has been applied to the lowest reported LC_{50} value of 6.2 mg/L for *Daphnia*. The $PNEC_{water}$ is 0.006 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{sediment}$ and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. The K_{ow} and K_{oc} of guar gum cannot be calculated using EPI Suite because the molecular weight of guar gum greatly exceeds the limit of 1,000. Thus, the equilibrium partition method cannot be used to determine a $PNEC_{soil}$ and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU Reach Criteria methodology (DEWHA, 2009; ECHA, 2008).

Guar gum is a naturally occurring polysaccharide from the guar plant or cluster bean; it expected to be readily biodegradable. Thus it is not expected to meet the screening criteria for persistence.

The potential to bioaccumulate in organisms is considered to be low. Thus guar gum is not expected to meet the criteria for bioaccumulation.

There are no adequate chronic aquatic toxicity studies available on guar gum. The acute LC_{50} values for guar gum are >1 mg/L in fish and invertebrates. Therefore, guar gum does not meet the screening criteria for toxicity.

The overall conclusion is that guar gum is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Aquatic Toxicity Category 2

B. Labelling

Warning!

According to the classification provided by companies to ECHA in CLP notifications, this substance causes serious eye irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Remove contaminated clothing. Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

Notes to Physician

May cause asthma-like (reactive airways) symptoms.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus for fire fighting.

C. Accidental Release Measures

Personal Precautions

Avoid dust formation.

Environmental Precautions

No special environmental precautions required.

Steps to be Taken if Material is Released or Spilled

Sweep up and dispose in suitable, closed containers.

D. Storage And Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard specifically for guar gum.

Engineering Controls

Ensure adequate ventilation.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Handle with gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Guar gum is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Biesinger, K.E., Lemke, A.E., Smith, W.E., and Tyo, R.M. (1976). Comparative toxicity of polyelectrolytes to selected aquatic animals. J. Water Pollut. Control Fed. 48: 183-187; cited in U.S. EPA ECOTOX database.

Collins, T.F.X., Welsh, J.J., Black, T.N., Graham, S.L., and O'Donnell, M.W., Jr. (1987). Study of the teratogenic potential of guar gum. Food Chem. Toxicol. 25: 807-814.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Food and Drug Research Laboratories, Inc. [FDRL]. (1973). Teratologic evaluation of FDA 71-16 (guar gum) in mice, rats, hamsters, and rabbits. Final report prepared under DHEW contract No. FDA 71-260. Maspeth, NY. NTIS No. PB-223-819/4; cited in CIR (2015).

Glickman M. (1969). Gum technology in the Food Industry, pp. 590, Academic Press, New York; cited in Yoon *et al.* (1998).

Graham, S.L., Arnold, A., Kasza, L., Ruffin, G.E., Jackson, R.C., Watkins, T.L., and Graham, C.H. (1981). Subchronic effects of guar gum in rats. Fd. Cosmet. Toxicol. 19: 287-290.

Johnson, W., Jr., Heldreth, B., Bergfeld, W.F., Belsito, D.V., Hill, R.A., Klaassen, C.D., Liebler, D.C., Marks, J.G., Jr., Shank, R.C., Slaga, T.J., Snyder, P.W., and Andersen, F.A. (2015). Safety assessment of galactomannans as used in cosmetics. Int. J. Toxicol. 34(Suppl. 1): 35S-65S.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lee, W.R., Abrahamson, S., Valencia, R., Von Halle, E.S., Wuergler, F.E., and Zimmering, S. (1983). The sex-linked recessive lethal test for mutagenesis in *Drosophila melanogaster*. A report of the U.S. Environmental Protection Agency Gene-Tox Program. Mutat. Res. 123: 183-279.

Malo, J.L., Cartier, A., L'Archevêque, J., Ghezzo, H., Soucy, F., Somers, J., and Dolovich, J. (1990). Prevalence of occupational asthma and immunologic sensitization to guar gum among employees at a carpet-manufacturing plant. J. Allergy Clin. Immunol. 86: 562-569.

McCarty, J.D., Weiner, M., Freeman, C., Aguinaldo, E.R., and Fletcher, M.J. (1990). Primary skin and ocular irritation studies on five food additive plant gums. J. Am. Coll. Toxicol. 1(1): 50-51.

NTP. (1982). NTP Technical Report on the Carcinogenesis Bioassay of Guar Gum (CAS No. 9000-30-0) in F344 Rats and B6C3F_1 Mice (Feed Study), National Toxicology Program, Research Triangle Park, NC.

PubChem. PubChem open chemistry database: https://pubchem.ncbi.nlm.nih.gov

United States Environmental Protection Agency [USEPA]. (2005). Science Assessment for Hydroxypropyl Guar Gum, Lower Risk Pesticide Chemical Focus Group, Office of Prevention, Pesticides and Toxic Substances, US Environmental Protection Agency. Accessed: http://www.epa.gov/opprd001/inerts/hydroxypropyl.pdf

Zeiger, E., Anderson, B., Haworth, S., Lawlor, T., and Mortelmans, K. (1992). Salmonella mutagenicity tests: V. Results from the testing of 311 chemicals. Environ. Mol. Mutagen. 21: 2-141.

HYDROCHLORIC ACID

This dossier on hydrochloric acid presents the most critical studies pertinent to the risk assessment of hydrochloric acid in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from OECD-SIDS documents (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Chlorane

CAS RN: 7647-01-0

Molecular formula: HCl

Molecular weight: 36.46 g/mol

Synonyms: Hydrochloric acid; HCl; chlorane; hydrogen chloride; muriatic acid; chlorohydric acid

SMILES: Cl

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Hydrochloric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless to slightly yellow gas of fuming liquid with pungent, irritating odour.	2	ECHA
Melting Point	-114.22°C	2	ECHA
Boiling Point	-85°C	4	ECHA
Density	1.639 kg/m^3 @ 0°C (gas) 1190 kg/m^3 @ 15°C (liquid)	4	ECHA
Vapour Pressure	4,104 kPa 4,723 kPa @ 25°C	4	ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble	4	ECHA
Viscosity	1.7 x 10^{-6} m^2s @ 20°C	1	ECHA

Hydrochloric acid can exist in a gaseous phase at room temperature and pressure. Hydrochloric acid is also very soluble in water and is a strong acid that dissociates completely in water to hydrogen (H^+) and chloride (Cl^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility, hydrochloric acid will be found predominantly in the aquatic environment where it dissociates completely to hydrogen (H^+) and chloride (Cl^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of hydrochloric acid to an aquatic ecosystem may decrease the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of hydrochloric acid into the aquatic environment from the use of HCl could potentially increase the chloride concentration and decrease the pH in the aquatic environment. Table 2 shows the amount of hydrochloric acid that would need to be added to bicarbonate solutions to obtain pH values of 6.0 and 4.0. The UNEP (1995) study reported that the 10th percentile, mean and the 90th percentile of bicarbonate concentrations in 77 rivers in North America, South America, Asia, Africa, Europe and Oceania were 20, 106, and 195 mg/L, respectively. The data show that the decrease in pH depends on the buffer capacity (bicarbonate concentration) of the receiving water. The calculated values in Table 2 were confirmed experimentally.

Table 2: Buffer capacity to maintain the pH based on bicarbonate concentration from UNEP monitoring data (de Groot and van Dijk, 2002; taken from OECD, 2002b)

Initial concentration of HCO_3^-	Final pH	Concentration of HCl required to obtain the final pH value
		Calculated (mg/L)
20 mg/L HCO_3^- (10th percentile 77 rivers)	6.0	8.28
	4.0	11.9
106 mg/L HCO_3^- (mean value of 77 rivers)	6.0	43.9
	4.0	63.2
195 mg/L HCO_3^- (90th percentile 77 rivers)	6.0	80.7
	4.0	116.3

H^+ and Cl^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002a,b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Hydrochloric acid is a corrosive liquid. Depending on the concentration, aqueous solutions of hydrochloric acid (HCl) are either corrosive, irritating or non-irritating to the skin, eyes and gastrointestinal tract. Vapours from aqueous solutions of HCl can cause respiratory irritation. HCl is not a skin sensitiser. Subchronic inhalation studies show localised irritation to the upper respiratory tract of rats and mice, but no systemic toxicity. No repeated dose toxicity studies have been conducted by the oral route. Positive findings have been reported in some *in vitro* genotoxicity studies, which are considered to be the result of the pH change in the test system. A lifetime inhalation study showed no carcinogenicity in rats exposed to HCl. No adequate reproductive or developmental studies have been conducted on HCl.

B. Acute Toxicity

The oral LD_{50} values in rats were reported to be 238 to 277 mg/kg and 700 mg/kg (OECD, 2002a,b) [Kl. scores = 2 and 4, respectively].

The lethal dose by dermal exposure is > 5,010 mg/kg for rabbits (OECD 2002a,b) [Kl. score = 4].

The LC_{50} values in rats for HCl gas are 40,989 and 4,701 ppm for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2]. The LC_{50} values in rats for HCl aerosol are 31,008 and 5,666 ppm (45.6 and 8.3 mg/L) for 5 and 30 minutes, respectively (ECHA) [Kl. score = 2].

C. Irritation

Application of a 37% aqueous solution of HCl for 1 or 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 2]. Application of 0.5 mL of a 17% solution of aqueous solution of HCl for 4 hours was corrosive to the skin of rabbits (OECD, 2002a,b) [Kl. score = 3]. Moderate skin irritation was observed in rabbits following an application of 0.5 mL of a 3.3% aqueous solution of HCl for five days; no irritation was observed with 0.5 mL of a 1% aqueous solution (OECD, 2002a,b) [Kl. score = 2]. In humans, an aqueous solution of 4% of HCl was slightly irritating, while a 10% solution was sufficiently irritating to be classified as a skin irritant (OECD, 2002a,b).

Instillation of 0.1 mL of a 10% aqueous solution of HCl to the eyes of rabbits resulted in severe eye irritation (ECHA) [Kl. score = 2]. Instillation of 0.1 mL of a 5% solution of HCl produced corneal opacity, iridial lesions, conjunctival redness and chemosis in 3/3 animals at 1 hour and at day one post-instillation. There was no recovery in any animal and the study was terminated on day two (ECHA) [Kl. score = 1].

D. Sensitisation

Hydrochloric acid was not a skin sensitiser in a guinea pig maximisation test (ECHA) [Kl. score = 2].

E. Repeated Dose Toxicity

Oral

No adequate studies were located.

Inhalation

Male and female SD rats and F344 rats were exposed by inhalation to 0, 10, 20, or 50 ppm 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm male F344 rats. There were no treatment-related effects on the haematology or clinical chemistry parameters or urinalysis. At study termination, heart, kidney and testes weights were increased in the 100 and/or 50 ppm groups; these changes were considered to be mainly related to the treatment-related effect on body weight. Histopathological examination showed minimal to mild rhinitis in the ≥ 20 ppm dose groups of both strains of rats (both sexes). The NOAELs for systemic toxicity and localised irritation (site-of-contact) are 20 and 10 ppm, respectively (ECHA) [Kl. score = 1].

Male and female B6C3F$_1$ mice were exposed by inhalation to 0, 10, 20 or 50 ppm HCl, 6 hours/day, 5 days/week for up to 90 days. Clinical signs were mainly indicative of the irritant/corrosive nature of HCl. Body weights were significantly decreased in the 50 ppm groups. At study termination, absolute liver weights were decreased in the 50 ppm males. Histopathologic examination showed only eosinophilic globules in the nasal epithelium in the 50 ppm animals. The NOAEL for this study is 20 ppm (ECHA) [Kl. score = 1].

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium (ECHA) [Kl. score = 2].

Dermal

No studies were located.

F. Genotoxicity

In Vitro Studies

Table 3 presents the *in vitro* genotoxicity studies on hydrochloric acid.

Table 3: *In Vitro* Genotoxicity Studies on Hydrochloric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	+	2	ECHA
Chromosomal aberration (CHO cells)	+	+	2	ECHA
Saccharomyces cerevisiae (mitotic recombination	-	-	2	ECHA
E. coli W3110 (pol A+) and P3078 (pol A-) repair assay	-	-	2	ECHA

* +, positive; -, negative

In the mouse lymphoma assay, the mutant frequency increased as the pH was lowered to 6.5 to 6.0 (from increased HCl) in the presence of metabolic activation. A decrease in pH from the addition of HCl to the medium also resulted in clastogenic effects to CHO cells in the absence or presence of metabolic activation. The positive findings in these two studies are considered to be the result of the pH change in the test media.

In Vivo Studies

No adequate studies were located.

G. Carcinogenicity

Oral

No studies were located.

Inhalation

Male SD rats were exposed by inhalation to 0 or 10 ppm HCl 6 hours/day, 5 days/week for 128 weeks. Survival and body weights were similar between treated and control groups. There was a higher incidence of hyperplasia of the larynx compared to control, but no serious irritating effects of the nasal epithelium. There was no increased incidence of tumours in the HCl-treated rats compared to controls (ECHA) [Kl. score = 2].

H. Reproductive Toxicity

No studies were located.

I. Developmental Toxicity

No adequate studies were located.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Repeated dose, reproductive and developmental toxicity studies by the oral route have not been conducted on hydrochloric acid. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of hydrochloric acid, which would limit the amount of absorbed HCl. Hydrochloric acid dissociates to hydrogen and chloride ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, an oral toxicological reference and drinking water guidance values were not derived from hydrochloric acid.

The Australian drinking water guideline values for pH (6.5 to 8.5) and chloride (250 ppm, aesthetics) may be applicable (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Hydrochloric acid does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

The hazard of hydrochloric acid for aquatic organisms is caused by the hydrogen ion (H^+). The toxicity values in terms of mg/L are not relevant because of the varying buffering capacity of different test systems and different aquatic ecosystems.

B. Aquatic Toxicity

Acute Studies

The acute aquatic toxicity studies on hydrochloric acid are listed in Table 4.

Table 4: Acute Aquatic Toxicity Studies on Hydrochloric Acid

Test Species	Endpoint	Results	Klimisch score	Reference
Lepomis macrochirus	96-hour LC_{50}	pH 3.25 – 3.5 (20 mg/L)	2	ECHA; OECD 2002a,b
Daphnia magna	48-hour EC_{50}	pH 4.92 (0.45 mg/L)	1	ECHA
Chlorella vulgaris	72-hour EC_{50} 72-hour EC_{10}	pH 4.7 [growth rate] (0.73 mg/L) PH 4.7 (0.364 mg/L)	1	ECHA

Chronic Studies

No chronic studies are available.

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

PNEC values were not derived from hydrochloric acid because factors such as the buffer capacity, the natural pH and the fluctuation of the pH are very specific for a certain ecosystem.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Hydrochloric acid is an inorganic salt that dissociates completely to hydrogen and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both hydrogen and chloride ions are also ubiquitous and are present in water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Hydrogen and chloride ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, hydrochloric acid is not expected to bioaccumulate.

No chronic toxicity data exist on hydrochloric acid. The acute EC_{50} values are > 1 mg/L in fish, < 1 mg/L for invertebrates and algae. Thus, hydrochloric acid meets the screening criteria for toxicity.

The overall conclusion is that hydrochloric acid is a PBT substance based on toxicity to invertebrates and algae.

IX. CLASSIFICATION AND LABELLING

A. Classification

For HCl concentrations of >25%:

- Metal Corrosive Category 1
- Skin Corrosive 1B
- STOT SE Category 3 [Respiratory irritant]

In addition to the hazard statements corresponding to the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

According to the classification provided by companies to ECHA in REACH registrations this substance causes severe skin burns and eye damage, is toxic if inhaled, may damage fertility or the unborn child, causes serious eye damage, may cause damage to organs through prolonged or repeated exposure, may be corrosive to metals and may cause respiratory irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

<u>Eye Contact</u>

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

<u>Skin Contact</u>

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of the body with soap and fresh water. Get medical attention immediately.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or another proper respiratory medical device. Give artificial respiration if the victim is not breathing. Get medical attention immediately.

Ingestion

Rinse mouth and lips with plenty of water if a person is conscious. Do not induce vomiting. Do not use mouth-to-mouth method if the victim ingested the substance. Obtain medical attention immediately if ingested.

Notes to Physician

Treat as corrosive due to pH of the material. All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use dry chemical, carbon dioxide, water spray or fog, or foam.

Specific Exposure Hazards

Containers may explode when heated. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following materials: halogenated compounds, may release dangerous gases (chlorine).

Special Protective Equipment for Firefighters

Structural firefighter's protective clothing provides limited protection in fire situations only; it is not effective in spill situations where direct contact with the substance is possible. Wear chemical protective clothing that is specifically recommended by the manufacturer. It may provide little or no thermal protection. Wear positive pressure self-contained breathing apparatus (SCBA). Move containers from the fire area if you can do it without risk.

C. Accidental Release Measures

Personal Precautions

Ventilate enclosed areas. Do not walk through spilt material. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours, or spray. Do not get in eyes, on skin, or on clothing.

Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas.

Steps to be Taken if Material is Released or Spilt

ELIMINATE all ignition sources (no smoking, flares, sparks or flames in immediate area). As an immediate precautionary measure, isolate spill or leak area for at least 50 meters in all directions. Keep unauthorised personnel away. Stay upwind. Keep out of low areas. Do not get water inside container.

D. Storage and Handling

General Handling

Handle and open container with care. Use only with adequate ventilation. Keep away from heat. Use caution when combining with water. DO NOT add water to corrosive liquid, ALWAYS add corrosive liquid to water while stirring to prevent the release of heat, steam and fumes. Wear appropriate personal protective equipment, avoid direct contact. Do not breath mist, vapours or spray. Do not get in eyes, on skin or on clothing. Do not ingest. Wash thoroughly with soap and water after handling and before eating, drinking or using tobacco.

Storage

Keep contain tightly closed. Store in a cool, dry, well-ventilated place. Keep away from incompatible materials. Keep from direct sunlight. Separate from alkalis. Do not store above 49°C/120°F.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for hydrochloric acid in Australia is 5 ppm (7.5 mg/m^3 as a peak limitation, with a sensitisation notation). A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. Use a properly fitted, air-purifying or air-fed respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection is based on known or anticipated exposure levels, the hazard of the product and the safe working limits of the selected respirator.

Hand Protection: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for

any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Skin Protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling hydrochloric acid.

Eye Protection: Wear chemical splash goggles and face shield.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Australian Dangerous Goods

UN 1789 (HYDROCHLORIC ACID)

Class: 8

Packing Group: II or III

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

de Groot, W.A., and van Dijk, N.R.M. (2002). Addition of hydrochloric acid to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals, Study No. A SOL.S.027; cited in OECD 2002a,b.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (2002a). IUCLID Data Set for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Hydrogen chloride (CAS No. 7647-01-0), UNEP Publications.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

ISOPROPANOL

This dossier on isopropanol presents the most critical studies pertinent to the risk assessment of isopropanol in its use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Propan-2-ol

CAS RN: 67-63-0

Molecular formula: C_3H_8O

Molecular weight: 60.1 g/mol

Synonyms: Isopropanol, isopropyl alcohol, 2-propanol, *sec*-propyl alcohol, dimethylcarbinol

SMILES: CC(C)O

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Isopropanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	2	ECHA
Melting Point	-88.5°C; -89.5°C[1]	2	ECHA
Boiling Point	82.5°C; 82.3°C @ 101.3 kPa	2	ECHA
Density	800 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	4,400 Pa @ 20°C; 6,002 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	0.05 @ 25°C	2	ECHA
Water Solubility	Miscible	2	ECHA
Viscosity	2.038 mPa s @ 25°C	2	ECHA

[1] No information on the atmospheric pressure reported.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Isopropanol is readily biodegradable. It is not expected to bioaccumulate. Isopropanol has a low tendency to bind to soil or sediment.

B. Partitioning

Isopropanol is miscible in water. Volatilisation from water surfaces or moist soil surfaces is expected to be an important fate process based upon this compound's estimated Henry's Law constant of 0.821 Pa m^3/mole. It is also expected to volatilise from dry soil surfaces based upon its vapour pressure (Pub Chem).

C. Biodegradation

Aerobic biodegradation of isopropanol has been shown to occur rapidly under non-acclimated conditions, based on a result of 49% biodegradation from a 5-day BOD test (Bridie et al., 1979). Additional biodegradation data developed using standardised test methods show that isopropanol is readily biodegradable in both freshwater and saltwater media (72 to 78% biodegradation in 20 days) (Price et al., 1974).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

No experimental data are available for isopropanol. Using KOCWIN in EPI Suite™ (USEPA, 2017), the estimated K_{oc} value from log K_{ow} is 3.478 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 1.53 L/kg.

E. Bioaccumulation

Bioconcentration of isopropanol in aquatic organisms is not expected to occur based on a measured log K_{ow} of 0.05 (ECHA). Based on this estimated value, the substance is expected to have very high mobility in soil. If released to water, based on this value and its water solubility, it is also not expected to adsorb to suspended solids and sediment.

Volatilisation from water surfaces is expected with half-lives for a model river and model lake of 86 hours and 29 days, respectively (PubChem).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

The acute toxicity of isopropanol is low by the oral, dermal and inhalation routes. At high exposure levels, isopropanol is irritating to the eyes, nose and throat and may cause transient central nervous system depression. It is not a skin sensitiser, but in some individuals, there may be an allergic contact dermatitis due to cross-sensitisation to other alcohols, such as ethanol. Repeated high exposures cause reversible narcotic effects, consistent with other short-chain alcohols. Isopropanol is not genotoxic. Lifetime inhalation studies in rodents showed no carcinogenic effects. The weight-of-evidence indicates that

isopropanol is not a reproductive toxicant. In a two-generation reproductive toxicity study, the male mating index was affected by isopropanol exposure; the significance of this effect is, however, unclear. Developmental toxicity can occur at maternally toxic doses; but it is not a teratogen. Isopropanol also does not affect neurobehavioral development.

B. Acute Toxicity

The acute oral LD_{50} of isopropanol has been reported as 4,700 mg/kg, 5,300 mg/kg, 5,500 mg/kg and 5,400 mg/kg in rats; 4,500 mg/kg in mice; and 5,030 mg/kg, 7,800 mg/kg and 7,900 mg/kg in rabbits (ECHA) [KI Score = 2].

The acute dermal LD_{50} in rabbits has been reported to be 12,900 mg/kg (ECHA) [KI Score = 2].

The acute inhalation 8-hour LC_{50} in rats was 19,000 ppm in females and 22,500 ppm in males (ECHA) [KI Score = 2]. Exposure of rats to 16,000 ppm for 8 hours resulted in four deaths out of six animals (ECHA) [KI Score = 2].

In an acute neurotoxicity study, male and female F344 rats were exposed to 0, 500, 1,500, 5,000 or 10,000 ppm isopropanol for 6 hours. A spectrum of behavioural effects indicative of narcosis, defined as a generalised loss of neuromotor and reflex function, was observed in animals of the 10,000 ppm group and to a lesser extent in the 5,000 ppm animals. Recovery from these effects was observed by 24 hours for the 10,000 ppm animals and by 6 hours for the 5,000 ppm animals. A concentration-dependent decrease in motor activity was observed for the 1,500 ppm males and the 5,000 ppm females. The results show that exposure of rats to isopropanol vapour produces transient, concentration-related narcosis and/or central nervous system sedation. The NOAEL for acute neurotoxicity is 500 ppm (ECHA) [KI Score = 2].

C. Irritation

Isopropanol applied to the intact or abraded skin of rabbits and guinea pigs produced negligible irritation. Liquid isopropanol is moderately irritating to the eyes of rabbits. Isopropanol produced little irritation when tested on the skin of six human subjects (ECHA) [KI Score = 1].

D. Sensitisation

There have been reports of isolated cases of dermal irritation and/or skin sensitisation. Except for three case reports, the positive reactions were observed on patch testing patients with contact dermatitis due to ethanol. These patients also had a positive reaction to ethanol.

E. Repeat Dose Toxicity

<u>Oral</u>

In a drinking water study, rats ingested 0.5 to 10% of isopropanol for 27 weeks and showed decreased body weight gain but no gross or microscopic tissue abnormalities (ECHA) [KI score = 3]. Increased formation of hyaline droplets in the proximal tubules was reported in male rats given 1–4% isopropanol in drinking water for 12 weeks (ECHA) [KI Score = 3].

A two-generation reproductive toxicity study has been conducted in rats given isopropanol by oral gavage. Pre-mating exposures were for at least 10 weeks for both generations. The results from this study are presented in the Reproductive Toxicity section (ECHA) [KI Score = 2].

Inhalation

F344 rats and CD-1 mice (both sexes) were exposed to 0, 100, 500, 1,500 or 5,000 ppm isopropanol for 6 hours/day, 5 days/week for 13 weeks. There were no deaths during the study. During and immediately following exposure to 5,000 ppm, ataxia, narcosis, hypoactivity and a lack of startle reflex were observed in some rats and mice. Narcosis was not observed in rats during exposure following week 2, suggesting some adaptation to isopropanol. During exposures to 1,500 ppm, narcosis, ataxia, and hypoactivity were observed in some mice, whereas only hypoactivity was observed in rats. Immediately following exposures, ataxia and/or hypoactivity were observed in a few rats or mice exposed to 5,000 ppm. Overall, the 1,500 and 5,000 ppm rats and the 5,000 ppm female mice showed increased body weights and/or body weight gain during the study. Liver weights relative to body weight were observed in rats of both sexes and the 5,000 ppm female mice; however, no corresponding microscopic changes were noted in the liver. Histopathological evaluation showed a slight increase in the size and frequency of hyaline droplets in the kidneys of the isopropanol-exposed rats. Excluding the clinical signs of CNS depression, the NOAEL for this study is 5,000 ppm (ECHA) [KI Score = 1].

In a subchronic neurotoxicity study, male and F344 rats were exposed by inhalation to 0, 100, 500, 1,500 or 5,000 ppm for 13 weeks. Neurobehavioural evaluations included a functional observation battery (FOB), motor activity and neuropathology. Effects of narcosis were observed in the 5,000 ppm groups only. There were no changes in FOB, but increased motor activity was noted in 5,000 female rats at weeks 9 and 13. Neuropathological examination revealed no exposure-related lesions in the nervous system. The NOAEL for acute effects is 500 ppm, and the NOAEL for subchronic neurotoxicity is 1,500 ppm (ECHA) [KI Score = 1].

An additional subchronic neurotoxicity study was conducted to clarify the increased motor activity findings. Female F344 rats were exposed to 0 or 5,000 ppm of isopropanol vapour for 6 hours/day, 5 days/week. Half of the animals in each group were exposed for 9 consecutive weeks and the other half for 13 consecutive weeks. After 9 weeks of exposure, the motor activity effect was reversible within 2 days after the last exposure. Subtle differences in the shape of the motor activity versus test session time curve were noted in both the 9-week and the 13-week exposed animals, although it was unclear whether these changes were treatment-related. Complete reversibility of these changes did not occur until 1 and 6 weeks after the last exposure in the 9 and 13 week exposure groups, respectively (ECHA) [KI Score = 2].

Male and female CD-1 mice were exposed by inhalation to 0, 500, 2,500 or 5,000 ppm isopropanol vapour 6 hours/day, 5 days/week for 18 months. An additional group of mice (all exposure levels) were assigned to a recovery group which were exposed to isopropanol for 12 months and then retained until study termination at 18 months. Survival was similar across all groups. Clinical signs were noted in the 5,000 ppm animals and included hypoactivity, lack of a startle reflex, ataxia, prostration and narcosis. Some of the animals in the 2,500 ppm group also showed hypoactivity, lack of a startle reflex and narcosis. Ataxia was the only exposure-related clinical sign that was noted for the 5,000 ppm animals

following exposure. There was a concentration-related increase in body weights and body weight gain in both the 2,500 and 5,000 ppm animals (both sexes). There were no exposure-related changes in the hematological parameters at the 12- and 18-month time points. At study termination, there was a concentration-related increase in liver weights in the females, with the 5,000 ppm females being statistically significant. Nonneoplastic lesions were limited to the testes (males) and the kidney. In the testes, enlargement of the seminal vesicles occurred in the absence of associated inflammatory or degenerative changes. The kidney effects included tubular proteinosis and/or tubular dilatation. The incidence of testicular and kidney effects was not increased in the isopropanol-exposed recovery animals. The NOAEL is 500 ppm (ECHA) [Kl Score = 2].

Male and female Fischer 344 rats were exposed to 0, 500, 2,500 or 5,000 ppm isopropanol vapour 6 hours/day, 5 days/week for 24 months. The mortality rates for all male rats were 82, 83, 91 and 100% for the 0, 500, 2,500 and 5,000 ppm groups, respectively. The corresponding values for the female rats were 54, 48, 55 and 69%. The main cause of death for the 5,000 ppm rats (both sexes), as well as for much of the mortality of the 2,500 ppm male rats, was chronic progressive nephropathy. Clinical signs were seen in the 5,000 ppm animals and included hypoactivity, lack of a startle reflex and narcosis. Some of the 2,500 ppm animals also showed a lack of a startle reflex. Body weight of the 5,000 ppm animals showed an initial decrease; from Weeks 6-72, body weights and body weight gain were increased. A similar pattern was seen in the 2,500 ppm males. Liver weights were increased in the ≥ 2,500 ppm male at 18 months, in the 2,500 ppm males at 24 months and in the 5,000 ppm females at 24 months. Kidney weights were increased in the 5,000 ppm males at 18 months and in the 5,000 ppm females at 24 months. Isopropanol exposure resulted in impaired kidney function, as indicated by various urine chemistry changes in male (2,500 and 5,000 ppm) and female (5,000 ppm) rats. Animals in these groups also exhibited histopathological effects in the kidneys which appeared to be an exacerbated form of chronic progressive nephropathy. The NOAEL is 500 ppm (ECHA) [Kl Score = 1].

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on isopropanol are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Isopropanol

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* TA98, TA100, TA1535, TA1537)	-	-	2	ECHA
Bacterial reverse mutation (*S. typhimurium* TA97, TA98, TA100, TA102, TA104, TA1535, TA1537, TA1538)	-	-	2	ECHA
Sister Chromatid Exchange (V79 cells)	-	-	2	ECHA
Mammalian cell gene mutation (CHO/HGPRT)	-	-	1	ECHA

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Adenovirus (SA7) cell transformation (Syrian hamster embryo cells)	NA	-	2	ECHA

*+, positive; -, negative; NA, not applicable

In Vivo Studies

Male and female ICR mice were given a single intraperitoneal injection of 0, 350, 1,173 or 2,500 mg/kg isopropanol. There were no increases in micronuclei in the bone marrow polychromatic erythrocytes at the 24, 48 or 72-hour post-dosing time points at any dose level (ECHA) [Kl Score = 1].

G. Carcinogenicity

Oral

No studies are available.

Inhalation

The carcinogenic potential of isopropanol was evaluated via inhalation using three strains of mice. Male mice were exposed to 7.5 ppm of isopropanol for 3 to 7 hours/day, 5 days/week for 5 to 8 months. Animals were killed at either 8 or 12 months. There was no significant increase in the number of lung tumours observed (ECHA) [Kl Score = 3].

Male and female CD-1 mice were exposed by inhalation to 0, 500, 2,500 or 5,000 ppm isopropanol vapour for 6 hours/day, 5 days/week for 18 months. An additional group of mice (all exposure levels) were assigned to a recovery group which were exposed to isopropanol for 12 months and then retained until study termination at 18 months. There was no increased frequency of neoplastic lesions in any of the isopropanol-exposed animals (ECHA) [Kl Score = 1].

Male and female Fischer 344 rats were exposed to 0, 500, 2,500 or 5,000 ppm of isopropanol vapour for 6 hours/day, 5 days/week for 24 months. The mortality rates for all male rats were 82, 83, 91 and 100% for the 0, 500, 2,500 and 5,000 ppm groups, respectively. The corresponding values for the female rats were 54, 48, 55 and 69%, respectively. The main cause of death for the 5,000 ppm rats (both sexes), as well as for much of the mortality of the 2,500 ppm male rats, was chronic progressive nephropathy. The only neoplastic lesion noted was increased interstitial (Leydig) cell adenomas in male rats. The frequency of these tumours, although elevated above the control animals, was within the historical control range of the testing facility and within the range reported for control animals from the National Toxicology Program carcinogenicity studies (ECHA) [Kl Score = 1].

H. Reproductive Toxicity

In a two-generation reproductive toxicity study, Sprague–Dawley rats were dosed by oral gavage with 0, 100, 500 or 1,000 mg/kg isopropanol. There were seven parental deaths that were considered treatment-related: two high-dose F_0 females, two F_1 high-dose females,

one mid-dose F_0 female, and two low-dose F_1 males. Lactation body weight gain was increased in the 500 and 1,000 mg/kg females in both generations, and liver and kidney weights were increased in the 500 and 1,000 mg/kg groups in both sexes. Centrilobular hepatocyte hypertrophy was noted in some 1,000 mg/kg F_1 males. There were some kidney effects in the 500 and 1,000 mg/kg F_0 males and in all treated F_1 male rats. The kidney effects were characterised by an increased number of hyaline droplets in the convoluted proximal tubular cells, epithelial degeneration and hyperplasia, and proteinaceous casts. Increased mortality occurred in the high-dose F_1 offspring during the early postnatal period; no other clinical signs of toxicity were observed in the offspring from either generation. Offspring body weight, however, in the 1,000 mg/kg group was reduced during the early postnatal period. There was significant mortality in the F_1 weanlings (18/70) before the selection of the F_1 adults. A statistically significant reduction was observed in the F_1 male mating index of the 1,000 mg/kg group (73 versus 97% in the controls). There were no other treatment-related effects on reproduction, including fertility and gestational indices, or histopathology of the reproductive organs. A benchmark dose level of 420 mg/kg/day was calculated (lower bound on dose associated with a 5% response rate) for the decrease in the male mating index (ECHA) [KI Score = 1].

In a one-generation reproductive/embryotoxicity study, male and female Wistar rats were given 0, 0.5, 1.0 or 2.0% isopropanol in their drinking water. The calculated intakes for males were 383, 686 and 1,107 mg/kg/day (pre-mating) and 347, 625 and 1,030 mg/kg/day (18 weeks of treatment). The calculated intakes for females were 456, 835 and 1,206 mg/kg/day (premating); 668, 1,330 and 1,902 mg/kg/day (gestation); and 1,053, 1,948 and 2,768 mg/kg/day (postpartum). An immediate, statistically significant dose-dependent decrease occurred in water intake in the male rats. Intake was reduced ~5-14% (1% group; premating period) and ~30% (2% group; days 7-11 to end of study). Overall mean feed consumption was significantly lower in treated versus control animals. Male body weights (2% only) were reduced throughout the study. Water consumption was initially reduced in the 1% and 2% females, but the 2% group recovered to only ~70% of the control values (premating); it continued to be reduced during the gestation and lactation period. Mean maternal body weights were reduced (all treated groups) at the start of gestation, with partial recovery during the gestation period except for the 2% group. Overall weight gain during gestation in these groups were similar to the controls. Following parturition from PND 4 onward, the 2% dams had significantly lower body weights. There were no infertile males in any group, and no treatment-related effect on female fertility or on length of gestation. The number of pups/litter on GD 1 was reduced in the 2% group; because it was not replicated in the embryotoxicity portion, an increase in pup mortality during parturition or GD 0, followed by cannibalism of the dead pups by the dam was suggested. No macroscopic abnormalities were seen in females; nor was there any treatment-related histopathological changes seen in the reproductive tissue in the 2% parental animals. Absolute kidney weight and relative kidney, liver and spleen weights were increased in the 2% F_0 males; increased absolute liver and kidney weights and relative liver weights in the 2% F_0 females. In the embryotoxicity portion, there was a statistically significant increase in the total number of pre-implantation losses in the 2% animals. Whole body oedema was seen in 40% of the foetuses in 3/8 litters in the 2% group. No macroscopic abnormalities of the viscera of these foetuses were detected, and the incidence of oedema was not related to gender. In the one-generation portion, postnatal pup survival and in the average pup weight (by PND 7) were decreased in the 2% group. F_1 generation animals of both sexes showed increased relative liver weights at all dose levels, and the 2% males had higher relative kidney weights. A slight but significant decrease in absolute brain weight and increase in relative empty cecum weights in both sexes of the 2% F_1 generation group was observed. No treatment-related gross

abnormalities were observed in the F_1 generation animals at necropsy. The NOAEL for reproductive toxicity is 2% in drinking water, the highest dose tested (ECHA) [KI Score = 1]. The effects of isopropanol (2.5% in drinking water) on the reproduction and growth of rats were assessed in a multigenerational study. No reproductive toxicity was observed. The NOAEL for reproductive toxicity is 2.5% isopropanol in drinking water (ECHA) [KI Score = 4].

Isopropanol was administered as a 3% solution in drinking water to Wistar rats. Reduced parental body weight gain, food, and water consumption were observed in the treated animals compared with the controls. Fertility, litter size and pup weights at postnatal days 4 and 21 were reduced in treated animals compared with the controls. In the second generation, the isopropanol concentration was reduced to 2%, and there were essentially no effects (ECHA) [KI Score = 4].

I. Developmental Toxicity

Oral Studies

Isopropanol was given at concentrations of 0, 0.5, 1.25 or 2.5% in the drinking water to female Wistar rats on GD 6 to 16. The calculated intakes of isopropanol during GD 6-16 were 596, 1,242 and 1,605 mg/kg/day. There was an immediate reduction in water intake in the 2.5% dose group, and this was statistically significant throughout the treatment period when compared to controls. A smaller reduction in water intake was also seen in the 1.25% females (statistically significant during GD 6-9), with no change in the 0.5% females. Palatability of the drinking water may have been the problem since water intake significantly increased the first day following the end of the treatment period for all dose groups. Feed consumption patterns paralleled the water consumption during and after treatment in the mid- and high-dose groups. Overall, mean body weights of the 2.5% females were lower than the controls from GD 7 to termination. Effects on weight gain in the 0.5% and 1.25% females were limited to a failure to gain weight during the first (0.5%) and second (1.25%) day of treatment. There were no treatment-related effects in post-implantation loss, mean number of implantation sites or live foetuses. There was a slight dose-dependent decrease in mean litter weight and a significant decrease in mean foetal weight in the 1.25% and 2.5% groups. A statistically significant increase in variations was observed, indicative of a lower degree of ossification in the treated animals. There was a dose-dependent decrease in the number of foetuses with the 4th sacral arch and a dose-dependent increase in the number of foetuses with less than 2 caudal arches. The sternum also showed reduced ossification because there were increased numbers of foetuses with small, absent or incompletely ossified sternebrae. The NOAEL for maternal and developmental toxicity is 596 mg/kg/day (ECHA) [KI Score = 1].

In a rat developmental study, female Sprague–Dawley rats were dosed by oral gavage with either 0, 400, 800 or 1,200 mg/kg of isopropanol during gestational days 6 to 15. Two dams (8%) died at 1,200 mg/kg and one dam (4%) died at 800 mg/kg. At 1,200 mg/kg, maternal body weights were reduced throughout gestation (GS 0-20; 89.9% of control value), associated with reduced gravid uterine weight. There were no other treatment-related effects on the dams. Foetal body weights per litter were also significantly reduced at the 800 and 1,200 mg/kg dose levels, but there were no teratogenic effects. The NOAEL for maternal and developmental toxicity is 400 mg/kg/day, respectively (ECHA) [KI Score = 1]. In a rabbit developmental study, female New Zealand white rabbits were dosed by oral gavage with either 0, 120, 240 or 480 mg/kg of isopropanol during gestational days 6 to 18. At 480 mg/kg, isopropanol was unexpectedly toxic to pregnant female rabbits, resulting in the deaths of four does (26%). Maternal body weights were significantly reduced during

treatment (gestational days 6–18) and were associated with reduced maternal food consumption during this period. Profound clinical signs were noted at 480 mg/kg and included flushed and/or warm ears, cyanosis, lethargy and laboured respiration. No adverse maternal effects were noted at 120 or 240 mg/kg. There were no developmental or teratogenic effects at any dose tested. The NOAELs for maternal and developmental toxicity are 240 and 480 mg/kg/day, respectively (ECHA) [KI Score = 1].

Isopropanol was given by oral gavage to Sprague–Dawley rats from gestational days 6 to 21 in doses of 0, 200, 700 or 1,200 mg/kg. The dams were allowed to deliver, litters were culled on postnatal day (PND) 4, pups were weaned on PND 22, and their dams were killed. Weaned pups were assessed for day of testes descent or vaginal opening, motor activity, auditory startle and active avoidance. The pups were killed on PND 68. Some of the pups were taken from each dose group and were perfused in situ for pathological examination of the central nervous system. There were no biologically significant findings in the behavioural tests, no changes in organ weights and no pathological findings of note. Thus, there was no evidence of developmental neurotoxicity from isopropanol exposure (ECHA) [KI Score = 1].

Inhalation Studies

Pregnant female Sprague Dawley rats were exposed to 0, 3,500, 7,000 or 10,000 ppm isopropanol for 7 hours/day during gestational days 1–19. The animals showed unsteady gait and narcotisation during initial exposures in the mid- and high-dose groups; reduced food consumption and reduced weight gain were also noted in both the mid- and high-dose groups. Foetal body weights per litter were reduced in all dose groups. Exposure to 10,000 ppm also resulted in failure of implantation, fully resorbed litters, increased resorptions per litter and increased incidence of cervical ribs. The NOAEL for maternal toxicity is 3,500 ppm. The LOAEL for developmental toxicity is 3,500 ppm; a NOAEL was not established (ECHA) [KI Score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for isopropanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-cancer

Oral

The repeated-dose toxicity studies on isopropanol by the oral route are inadequate for the purposes of risk assessment. There is, however, a well-conducted two-generation reproductive toxicity study, in which rats were dosed by oral gavage up to 1,000 mg/kg/day (Bevan et al., 1995). Allen et al. (1998) calculated a benchmark dose level of 420 mg/kg/day (lower bound on dose associated with a 5% response rate for the decrease in the male mating index). The Point of Departure (POD) of 420 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1
Oral RfD = 420/(10 x 10 x 1 x 10 x 1) = 420/1000 = 0.4 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (0.4 x 70 x 0.1)/2 = 1.4 mg/L

B. Cancer

Isopropanol was not carcinogenic to rats or mice in chronic inhalation studies. Therefore, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Isopropanol is a flammable liquid.

Isopropanol does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Isopropanol is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on isopropanol.

Table 3: Acute Aquatic Toxicity Studies on Isopropanol

Test Species	Endpoint	Results	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	9,640 mg/L	2	ECHA
Daphnia magna	24-hour EC_{50}	> 10,000 mg/L	2	ECHA

Chronic Studies

Table 4 lists the results of chronic aquatic toxicity studies on diethanolamine.

Table 4: Chronic Aquatic Toxicity Studies on Isopropanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Daphnia magna	16-day NOEC	141 mg/L	4	ECHA
Daphnia magna	21-day NOEC	30 mg/L	4	OECD, 1977a,b
Scenedesmus quadricauda	7-day NOEC	1,800 mg/L	2	ECHA

C. Terrestrial Toxicity

An EC_{50} value of 2,100 mg/L was determined from a lettuce seed germination test (Reynold, 1977) [Kl score = 2].

D. Calculation of PNEC

The PNEC calculations for isopropanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute $E(L)C_{50}$ values are available for fish (9,640 mg/L) and invertebrates (> 10,000 mg/L). Results from chronic studies are available for invertebrates (16- and 21-day NOECs for *Daphnia* are 141 and 30 mg/L, respectively). On the basis that the data consists of acute studies from two trophic levels and a chronic study from one trophic level, an assessment factor of 100 has been applied to the lowest reported NOEC of 30 mg/L for invertebrates. The $PNEC_{water}$ is 0.3 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 0.2 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.87/1280) \times 1000 \times 0.3$
$= 0.2$ mg/kg

Where:

$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water}$ = 0.8 + [0.2 x Kp_{sed})1000 x BD_{solid}]
= 0.8 + [0.2 x 0.14/1000 x 2400]
= 0.87 m^3/m^3

Where:

Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
Kp_{sed} = K_{oc} x f_{oc}
= 3.478 x 0.04
= 0.14 L/kg

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for isopropanol calculated from EPI Suite™ using Log K_{ow} is 3.478.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.014 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil}$ = (Kp_{soil}/BD_{soil}) x 1000 x $PNEC_{water}$
= (0.07/1500) x 1000 x 0.3
= 0.014 mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
Kp_{soil} = K_{oc} x f_{oc}
= 3.478 x 0.02
= 0.07 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for isopropanol calculated from EPI Suite™ using K_{ow} is 3.478 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Isopropanol is readily biodegradable; thus, it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 0.05 and a calculated BCF of 1, isopropanol does not meet the screening criteria for bioaccumulation.

The chronic toxicity data on isopropanol show a NOEC of > 0.1 mg/L. The acute E(L)C_{50} values for isopropanol are > 1 mg/L. Thus, isopropanol does not meet the screening criteria for toxicity.

The overall conclusion is that isopropanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 2

Eye Irritant Category 2

STOT Single Exposure Category 3 [Narcosis]

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. If respiratory irritation, dizziness, nausea or unconsciousness occurs, seek immediate medical assistance. Give artificial respiration if victim is not breathing. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

If ingested, material may be aspirated into the lungs and cause chemical pneumonitis. Treat appropriately.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide. Do not use straight streams of water.

Specific Exposure Hazards

Highly flammable. Vapours are flammable and heavier than air. Vapours may travel across the ground and reach remote ignition sources causing a flashback fire danger. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. All equipment used when handling the material must be grounded. A vapour suppressing foam may be used to reduce vapours. Use clean non-

sparking tools to collect absorbed material. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Prevent exposure to ignition sources (i.e., use non-sparking tools and explosion-proof equipment). Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation. Use proper bonding and/or ground procedures. However, bonding and grounds may not eliminate the hazard from static accumulation. Peroxides may form upon prolonged storage. Exposure to light, heat or air significantly increases peroxide formation. If evaporated to a residue, the mixture of peroxides residue and material vapour may explode when exposed to heat or shock.

Storage

Keep container tightly closed. Store in a cool, well-ventilated area away from heat and light. Storage containers should be grounded and bonded. Fixed storage containers, transfer containers and associated equipment should be grounded and bonded to prevent accumulation of static charge. See SDS for suitable materials and coatings.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for isopropanol in Australia is 400 ppm as an 8-hour TWA and 500 ppm as a 15-min STEL.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN 1219 (Isopropanol)

Class 3

Packing Group II

XI. DISPOSAL

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Allen, B; Gentry, R; Shipp, A; Van Landingham, C. (1998). Calculation of benchmark doses reproductive and developmental toxicity observed after exposure to isopropanol. Regul Toxicol Pharmacol 28: 38-44. http://dx.doi.org/10.1006/rtph.1998.1226

Bevan C., Tyler T.R., Gardiner T.H., Kapp Jr. R.W., Andrews L. and Beyer B.K. (1995). Two generation reproductive toxicity study with isopropanol in rats. J. Appl. Toxicol. 15(2):117-123.

Bridie, A.L., Wolff, C.J.M., and Winter, M. (1979). BOD and COD of some petrochemicals. Water Res. 13: 627-630.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

OECD. (1997a). IUCLID Data Set for 2-Propanol (CAS No. 67-63-0), UNEP Publications.

OECD. (1997b). Screening Information Dataset (SIDS) Initial Assessment Report for 2-Propanol (CAS No. 67-63-0), UNEP Publications.

Price, K.S., Waggy, G.T., and Conway, R.A. (1974) Brine shrimp bioassay and seawater BOD of petrochemicals. J. Water Pollut. Contr. Fed., 46: 63-77.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

Reynold, T. (1977). An anomalous effect of isopropanol on lettuce germination. Plant Sci. Lett. 15: 25-28.

USEPA. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

MAGNESIUM SILICATE HYDRATE (TALC)

This dossier on magnesium silicate hydrate (talc) presents the most critical studies pertinent to the risk assessment of this substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dioxosilane; oxomagnesium; hydrate

CAS RN: 14807-96-6

Molecular formula: $H_2Mg_3O_{12}Si_4$

Molecular weight: 379.27 g/mol

Synonyms: Talcum, oxosilanediol, trimagnesium; dioxido(oxo)silane; hydroxy-oxido-oxosilane, dioxosilane; oxomagnesium; hydrate

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Magnesium Silicate Hydrate (Talc)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White solid odorless powder	2	ECHA
Melting Point	1,500°C @ 101.3 kPa	2	ECHA
Boiling Point	This substance is a solid that melts above 300°C	-	-
Density	2700 kg/m³ @ 20°C	2	ECHA
Vapour Pressure	0 Pa at 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-9.4 @ 25°C	2	ECHA
Water Solubility	0.0001 g/L @ 25°C; insoluble in water	2	ECHA
Flash Point	ND	-	-
Auto flammability	ND	-	-
Viscosity	Not applicable as substance is a solid.	2	ECHA
Dissociation constant	ND because the substance is insoluble in water	-	ECHA

ND – not determined

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Magnesium silicate hydrate (talc) is an inorganic substance for which biodegradation is irrelevant. Moreover, it will not bioaccumulate and has a low potential to adsorb to soil.

B. Biodegradation

As an inorganic substance, magnesium silicate hydrate (talc) will not biodegrade. Soil and sediment degradation studies are not considered to be applicable as the test material is essentially insoluble in water and consists of materials which occur naturally in these compartments (ECHA).

C. Environmental Distribution

Magnesium silicate hydrate (talc) is insoluble in water. The log K_{OC} of was estimated to be 1.5027 which is equal to a K_{OC} value of 31.82 L/kg using the KOCWIN v2.00 QSAR method (ECHA). Based on this K_{oc} value, if released to soil, magnesium silicate hydrate (talc) is expected to have a low potential for adsorption. If released into water, the substance has a low potential for adsorption to sediment or suspended solids.

D. Bioaccumulation

There is no potential for bioaccumulation. Due to its inherent chemical-physical properties, such as absence of lipophilicity as well as the capability of the organism to excrete absorbed SiO_2 components, bioaccumulation can be disregarded. Magnesium is widespread in living cells and does not bioconcentrate in aquatic organisms (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Talc is a mineral composed of hydrated magnesium silicate. Talc is essentially non-toxic by the oral and dermal routes. Talc is non-irritating to the eyes and skin. There was no toxicity or carcinogenic effects in rats. Talc is not genotoxic. No developmental toxicity was reported in pregnant female rats, mice or rabbits given oral doses of talc.

B. Basic Toxicokinetics

Inhalation

To determine the deposition, distribution and clearance of talc, 44 female Syrian golden hamsters received a single 2-hour nose-only exposure to a neutron-activated talc aerosol and sub-groups of 4 animals were then killed at 11 different intervals from 15 minutes to 132 days after exposure.

The talc tested was a commercial baby powder. Nine unexposed control animals were used; four were killed on the day the test animals were exposed and five were killed on the final day of the study. The aerosol exposure system had 7 tiers of exposure ports, and the talc aerosol was passed through a cyclone elutriator to remove particles that were larger than ~10 µm in diameter; the activity median aerodynamic diameter was 6.4-6.9 µm. The mean aerosol concentration was 40 and 75 µg/L at the 15 to 30 and 60 to 90-minute sampling periods, respectively. In the presentation of the results, the γ-ray counts from the controls were expressed as µg talc equivalent, and the γ-ray counts of the exposed animals were not corrected for control values.

Variations among animals killed at the same time were attributed to variations in aerosol concentration at different tiers. The mean pulmonary talc content in the lungs of test animals at various time intervals was 33.08 µg (15 minutes after exposure), 24.08 µg (100 minutes), 42.70 µg (4 hours), 18.75 µg (21 hours), 21.30 µg (2 days), 21.03 µg (after 4 days), 13.85 µg (after 8 days) and 8.95 µg (after 18 days); the mean for the Day 0 control animals was 1.78 µg. The biological half-life

of the talc deposited in the lungs was 7 to 10 days. At the time of termination of the final group, i.e., 132 days, there was no statistically significant difference in the talc burden of the lungs of test (3.70 µg) and control (2.30 µg) animals. The amount of talc in the liver, kidneys and lungs was also determined; the only statistically significant differences compared to controls in any of these organs were found in the liver. There was a decrease at 4 hours compared to day 0 controls, an increase at Day 36 compared to both Day 0 and Day 132 controls, and an increase on Day 68 compared to Day 132 controls.

Analysis of the data using the Kruskal-Wallis test showed that there were no significant differences among the mean talc burden values for the liver, kidneys and ovaries, including the control values, and that there was no significant trend, indicating there was no translocation of talc to these tissues.

As noted, no translocation from the respiratory tract to other tissues was found in this study, and the clearance of talc from the lungs was complete within 4 months after exposure.

Oral

In one study, six female Syrian golden hamsters (outbred Ela:ENG strain) were dosed by gavage with 1 mL neutron-activated talc suspended in physiological saline containing 0.6% (w/w) 1% methyl cellulose, and the animals were killed 24 hours after dosing. The talc used was a commercial baby powder.

Four hamsters were dosed similarly with a non-irradiated talc solution. The neutron-activated talc was exposed to an integrated neutron flux of 7 x 1,016 n/cm^2 30 days prior to dosing. The skinned carcass, gastrointestinal (GI) tract, lungs, liver, kidneys and excreta were analysed for isotopes 60 Co and 46 Sc by gamma-ray spectrometry, and the gamma-ray counts were compared with those of four hamsters that were not dosed with talc.

The γ-ray counts of the tissue and excreta of the dose animals were equivalent to a total of 2.94 mg talc. Based on γ-ray counts, 74.5% of the neutron-activated talc was recovered in the faeces and 23.5% was recovered in the GI tract, while 1.91% was recovered in the skinned carcass, 0.09% in the urine, 0.04% in the kidneys and 0.02% in the liver. The amount found in the urine of the hamsters given irradiated talc was statistically significantly increased compared to the controls. No talc was recovered in the lungs (ECHA) [KI score = 2].

In a second oral study, four LACA female mice were given a single oral dose of 40 mg/kg [3H] talc. Two mice were killed at 6 hours and two at 24 hours after dosing. In the mice killed 6 hours after dosing, 95 and 96% of the radioactivity was recovered in the large intestines and faeces, 9 and 7% was recovered in the small intestines and stomach, and 0.7 and 0% in the urine of each mouse. In the two mice killed 24 hours after dosing, 99 and 101% of the radioactivity was recovered in the large intestines and faeces, 4 and 6% was recovered in the small intestines and stomach, and 1.3 and 1.5% in the urine of each mouse. Less than 0.005% of the radioactivity was found in the carcass of any of the mice (ECHA) [KI score = 2].

In a third oral study, three male Wistar albino rats were given a single oral dose and three rats were given six daily oral doses by gavage of 50 mg/kg body wt [3H] talc. After the last dose, urine and faeces were collected every 24 hours for 4 days and on Day 10; the rats were then killed. Within 24 hours after administration of the single dose, approximately 75% of the radioactivity was recovered in the faeces and only 1% was recovered in the urine. After 96 hours, a total of 95.8% of the dose was excreted in the faeces and 1.7% in the urine, with a total excretion of 97.5% of the dose. No radioactivity was recovered in the liver or kidneys 10 days after a single dose of talc. On Day 10 in

the rats given six daily doses of [3H] talc, there was no radioactivity found in the faeces or livers, and there was a trace of radioactivity (< 0.02%) in the kidneys of these rats (ECHA) [Kl score = 2].

C. Acute Toxicity

Oral

A single oral dose of 5,000 mg/kg of talc prepared as an 18.3% (w/v) suspension in saline was administered to 10 male rats. All animals survived, and there were no signs of toxicity. In conclusion, the median lethal dose of Talc (Mg3H2(SiO3)4) after a single oral administration to male rats, observed over a period of 14 days is: LD50 > 5,000 mg/kg body weight (ECHA) [Kl Score = 2].

Inhalation

Groups of 5 male and female Wistar rats were treated with magnesium hydroxide as aerosol during 4 hours. No mortality or other relevant adverse effects were observed. An inhalatory LC_{50} (4-hour) value for magnesium hydroxide exceeding 2.1 mg/L was determined, being the maximum feasible concentration that could be tested (ECHA) [Kl Score = 2].

Dermal

An OECD Guideline 402 (Acute Dermal Toxicity) was performed. Five males and five female Wistar rats were dermally exposed to a single talc dose of 2,000 mg/kg.

Approximately 24 hours before the test, the fur was removed from the dorsal area of the trunk using an electric clipper. Care was taken to avoid abrading the skin, and only animals with healthy intact skin were used. No less than 10% of the body surface was cleared for the application.

The test item was applied at a single dose, uniformly over an area which was approximately 10% of the total body surface. The test item was held in contact with the skin throughout a 24-hour period. At the end of the exposure period the residual test item was not removed.

Under the conditions of this study, single dermal application of the test item magnesium chloride hexahydrate to rats at a dose of 2,000 mg/kg body weight was associated with no mortality. The dermal LD_{50} was determined to be > 2,000 mg magnesium chloride hexahydrate/kg body weight (ECHA) [Kl Score = 2].

Dermal

No studies were available.

D. Irritation

Skin

An *in vitro* skin irritation test was carried out with the reconstituted three-dimensional human skin model EPISKIN-SM™ (Skinethic). This skin model consists of normal (non-cancerous), adult human-derived epidermal keratinocytes (NHEK) which have been cultured to form a multilayered, highly differentiated model of the human epidermis. The NHEK are cultured on chemically modified, collagen-coated cell culture inserts. A highly differentiated and stratified epidermis model is

obtained after a 13-day culture period and is comprised of the main basal, supra basal, spinous and granular layers and a functional stratum corneum.

The test item showed no irritant effects. The mean relative tissue viability (% negative control) was ≥ 50% (112.9%) after 15-minute treatment and 42-hour post incubation. The controls confirmed the validity of the study. The mean OD550 of the three negative control tissues was ≥ 0.6. The mean relative tissue viability (% negative control) of the positive control was ≤ 30% (22.6%). The standard deviation of replicate tissues of all dose groups was ≤ 30% (1.4% - 9.4%). It can be concluded that talc is non-irritating to skin (ECHA) [KI Score = 2].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) study was performed using magnesium chloride hexahydrate as a surrogate substance for talc. A dose of 0.1 g of the test item was applied at a single dose in the conjunctival sac of one eye of each test animal after pulling the lower lid away from the eyeball. The lids were then gently held together for about 1 second in order to prevent loss of the material. The untreated contralateral eye served as control. Observations of the eye were made at 1, 24, 48 and 72 hours and 4 to 6 days.

Under the conditions of the study, single ocular instillation of the test item magnesium chloride hexahydrate to rabbits at a dose of 0.1 g produced irritant effects, which were fully reversible. Neither mortalities nor significant clinical signs of toxicity were observed. The test item is deemed to be non-irritating to eyes (ECHA) [KI Score = 2].

E. Sensitisation

No experimental data are available on the Talc ($Mg_3H_2(SiO_3)_4$) powder and silicates; however, there is long experience in humans. Data collected from industrial hygiene surveillance over the last 50 years do not indicate any potential for skin sensitisation. Despite the widespread cosmetic use of talc and special studies in volunteers (BIBRA, 1991) there are no indications of any allergenic effect (ECHA) [KI score = 3].

F. Repeated Dose Toxicity

Oral

A study equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies) was performed using male and female Wistar rats. Wistar rats (16 male and 16 female) were exposed to talc in feed which resulted in an amount taken up of 100 mg/kg/day. After feeding had been carried out for 101 days, the animals were observed until death and subsequently examined histopathologically.

One of the animals treated with talc showed a leiomyosarcoma of the stomach. Sarcomas, which were not associated with the talc treatment, were found in the uterus of two animals. No chronic pathological effect was associated with oral administration of talc over 5 months. No adverse effects were seen on general toxicity endpoints. Under the condition of this study, for a period of 101 days for male and female rats, the NOAEL of talc in a feeding study was 100 mg/kg/day (ECHA) [KI score = 2].

Inhalation

A study equivalent or similar to OECD Guideline 452 (Chronic Toxicity Studies) was performed using male and female Wistar rats. The Wistar rats (12 male and 12 female) were exposed whole body to aerosolised talc at a mean respirable dust concentration of 10.8 mg/m^3 for 7.5 hours per day, 5 days a week for 6 or 12 months.

Ten days after the end of each exposure period, 6 rats per group were killed; 12 rats per group died and 2 rats per group were unaccounted for. The remaining 4 rats per group were killed one year after the end of the exposure period. Minimal fibrosis was observed. Talc exposure led to distinct fibrosis that was comparable with that after exposure to chrysotile in the parallel group. A lung adenoma was detected in 1 of 24 animals treated with talc. In rats exposed by inhalation to 10.8 mg/m^3 Italian talc (grade 00000; ready milled; mean particle size, 25 µm) for 3 months, minimal fibrosis was observed, the degree of which did not change during the observation period after exposure. Animals that were exposed for 1 year had minimal to slight fibrosis, the degree of which had increased to moderate within 1 year after cessation of exposure.

A no observed adverse effect concentration (NOAEC) of 10.8 mg/m^3 was determined (ECHA) [KI Score = 2].

Dermal

No adequate studies for human health risk assessment are available.

G. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on talc are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Talc

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Mammalian cell gene mutation (rat pleural mesothelial cells (RPMC)).	-*	ND	2	ECHA

*+, positive; -, negative
ND – not determined

Talc did not cause a statistically significant increase in sister chromatid exchanges (SCEs) and was not clastogenic. The test substance is non-mutagenic under the given experimental conditions (ECHA) [KI Score = 2].

In Vivo Studies

A study equivalent or similar to OECD Guideline 478 (Genetic Toxicology: Rodent Dominant Lethal Test) was performed per a rat dominant lethal assay on Sprague Dawley rats. Groups of 10 male rats were dosed by gavage with a single dose or once daily for 5 days with 30, 300, 3,000 or 5,000 mg/kg talc.

There were no dose-response or time trend patterns; talc did not induce dominant lethal mutations in this assay. Therefore, talc was not genotoxic in a rat dominant lethal assay (ECHA) [KI Score = 2].

H. Carcinogenicity

Oral

An OECD Guideline 453 (Combined Chronic Toxicity / Carcinogenicity Studies) was performed. In a feeding study of 16 male and 16 female Wistar rats, talc was added to the diet; this resulted in a dosage rate of 100 mg/kg/day. After feeding had been carried out for 101 days, the animals were observed until death (approximately 614 days) and subsequently examined histopathologically. One of the animals treated with talc showed a leiomyosarcoma of the stomach. Sarcomas, which were not associated with the talc treatment, were found in the uterus of two animals.

However, no differences in tumour incidence were noted between treated animals and 8 male and 8 female control animals fed basal diet throughout (average survival, 641 days).

Inhalation

In a lifetime experiment, three groups of 50 male and 50 female Syrian golden hamsters, 4 weeks of age, were exposed (whole body) by inhalation to an aerosol of talc baby powder that was prepared from Vermont talc by flotation (95% w/w platy talc with trace quantities of magnesite, dolomite, chlorite and rutile) for 3, 30 or 150 minutes per day, 5 days a week for 30 days. The mean aerosol concentration was 37.1 mg/m^3, with a measurable respiratory fraction of 9.8 mg/m^3 and a MMAD of 4.9 µm. A placebo exposed group comprised 25 males and 25 females. Two further groups of hamsters, 7 weeks of age, were exposed to talc aerosol for 30 or 150 minutes per day for 300 days. The mean aerosol concentration was 27.4 mg/m^3, with a measurable respiratory fraction of 8.1 mg/m^3 and a MMAD of 6.0 µm. Another placebo-exposed group comprised 25 males and 25 females. The survivors of the last two talc-exposed groups were killed at the age of 20 months.

No clinical signs of toxicity to talc were observed. The type, incidence and severity of lesions indicated no trend toward a dose-response and no statistically significant differences between exposed and control groups. The incidence of focal alveolar cell hyperplasia (25% in treated groups; 10% in controls) appeared to be affected by treatment, but a two-way weighted analysis showed no significant association. Thus, exposure of hamsters to talc via inhalation did not produce carcinogenic effects (ECHA) [KI Score = 2].

I. Reproductive Toxicity

An OECD Guideline 416 (Two-Generation Reproduction Toxicity Study) was performed. Groups of 12-15 gravid Dutch-belted female rabbits were dosed orally with 9, 42, 195 or 900 mg/kg bw talc in corn oil on Days 6-18 of gestation. Eight gravid negative controls were given only vehicle and nine gravid positive controls were dosed with 2.5 mg/kg bw of 6-aminonicotinamide on Day 9 of gestation. The dams were killed on Day 29 of gestation. A total of 1/8, 4/15, 2/12, 5/15 and 2/13 dams of the negative control, 9, 42, 195 and 900 mg/kg bw dose groups, respectively, died or aborted before Day 29 of gestation, and the number of live litters for these groups was 6/7, 10/11, 8/10, 10/10 and 7/11, respectively. Details on Results (PO): Administration of up to 900 mg/kg bw talc on Days 6-18 of gestation had no discernible effect on nidation or on maternal survival.

The number of abnormalities did not differ between test and control animals.

Details on Results (F1): Administration of up to 900 mg/kg bw talc on days 6-18 of gestation had no discernible effect on nidation or on foetal survival. The number of abnormalities did not differ between test and control animals.

The NOAEL was considered to be 900 mg/kg bw/day for reproduction toxicity study. A NOAEL of > 900 mg/kg/day was determined for reproduction (ECHA) [KI Score = 2].

J. Developmental Toxicity

A GLP compliant study was performed. Groups of 20-22 gravid albino CD-1 mice and groups of 20-24 gravid Wistar rats were dosed by gavage with 0, 16, 74, 350 or 1,600 mg/kg bw talc as an anhydrous corn oil suspension on days 6-15 of gestation. The mice were killed on Day 17 and the rats on Day 20 of gestation and the number of implantation sites, resorptions sites, and live and dead foetuses, and the live pup body weights were recorded.

Maternal Toxicity: The administration of up to 1,600 mg/kg bw talc in corn oil had no effect on maternal endpoints.

Embryotoxic / Teratogenic Effects: The administration of up to 1,600 mg/kg bw talc in corn oil had no effect on developmental parameters and had no effect on foetal survival.

The NOAEL was considered to be 1,600 mg/kg bw/day for developmental toxicity (ECHA) [KI score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for talc follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

<u>Oral</u>

The NOAEL of 100 mg/kg/day from a chronic feeding study in rats was used to determine the oral RfD and drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 10
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 100/(10 x 10 x 1 x 1 x 1) = 100/100 = 1 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:
Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

The carcinogenicity studies suggest talc is not a carcinogen. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Talc does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Talc is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Table 3 lists the results of the acute aquatic toxicity studies on magnesium silicate hydrate (talc).

Table 3: Acute Aquatic Toxicity Studies on Talc

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Fish (species unnamed)	96-hour LC_{50}	89,581 mg/L (QSAR)	2	ECHA
Daphnid	48-hour LC_{50}	36,812 mg/L (QSAR)	2	ECHA
Algae (species unnamed)	96-hour LC_{50}	7,203 mg/L	1	ECHA

Chronic Studies

No data are available. Short term aquatic toxicity tests reported in the literature on fish (LC_{50} *Brachydanio rerio* (Zebra fish) >100,000 mg/L/24 hr; for talc) show this substance is not toxic to aquatic life. On this basis the need for long term aquatic testing is waived (ECHA).

C. Terrestrial Toxicity

No data are available.

D. Calculation of PNEC

PNEC calculations for talc follow the methodology discussed in DEWHA (2009).

PNEC water

Acute experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (89,581 mg/L), *Daphnia* (36,812 mg/L), and algae (7,203 mg/L). By applying an assessment factor of 100 to the lowest E(L)C_{50} value of 7,202 mg/L from the acute studies, the $PNEC_{water}$ for talc is 72 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Moreover, the low K_{ow} indicates that talc is not expected to partition to sediments. Therefore, a $PNEC_{sed}$ was not calculated.

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Moreover, talc is biodegradable and due to its low K_{ow}, is not expected to partition to soil. Therefore, a $PNEC_{soil}$ was not calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Magnesium silicate hydrate (talc) is an inorganic substance and thus, biodegradation is not relevant. For the purposes of this PBT assessment, the persistent criteria are not considered applicable for this substance.

No data are available on bioaccumulation. However, based on the low log K_{ow}, and the inherent chemical-physical properties of magnesium silicate hydrate (talc), bioaccumulation is not expected. Thus, magnesium silicate hydrate (talc) does not meet the screening criteria for bioaccumulation.

Chronic aquatic toxicity data is not available. The E(L)C_{50} values from the acute aquatic toxicity studies on magnesium silicate hydrate (talc) are > 1 mg/L. Thus, magnesium silicate hydrate (talc) does not meet the criteria for toxicity.

Therefore, magnesium silicate hydrate (talc) is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H332- Harmful if inhaled.

B. Labelling

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Rinse out mouth then drink plenty of water. Get medical attention.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Magnesium oxide, silicon oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Avoid dust formation. Avoid breathing vapours, mist of gas. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

No specific environmental precautions required.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage and Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light. Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has established an occupational exposure standard for exposure to talc of an 8 hour time weighed average (TWA) exposure limit of 2.5 mg/m^3 (containing no asbestos fibres).

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to

maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products, as well as before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Talc is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council

BIBRA. (1991). The British Industrial Biological Research Association (BIBRA) Toxicity Profile – Talc. BIBRA, Carshalton, GB.

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

European Chemicals Agency [ECHA] (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

METHANOL

This dossier on methanol presents the most critical studies pertinent to the risk assessment of methanol in its use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on methanol (OECD, 2004a,b), and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Methanol

CAS RN: 67-56-1

Molecular formula: CH_4O

Molecular weight: 32.04 g/mol

Synonyms: Methyl alcohol, carbinol, wood spirits, wood alcohol, methylol, wood, columbian spirits, colonial spirit, columbian spirit, methyl hydroxide, monohydroxymethane, pyroxylic spirit, wood naphtha.

SMILES: CO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Physico-Chemical Properties of Methanol

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Colourless liquid	2	ECHA
Melting Point	-97.8°C @ 101.3 kPa	2	ECHA
Boiling Point	64.7°C @ 101.3 kPa	2	ECHA
Density	790 kg/m^3@ 20 °C	2	ECHA
Vapour Pressure	16927 Pa @ 25 °C	2	ECHA
Partition Coefficient (log P_{ow})	-0.77	2	ECHA
Water Solubility	>1,000 g/L [miscible]	2	ECHA
Flash Point	9.7°C	2	ECHA
Auto flammability	455°C @ 101.3 kPa	2	ECHA
Viscosity	0.544 – 0.59 mPa s (dynamic)	2	ECHA
Henry's Law Constant	0.461 Pa m^3/mol @ 20 °C	2	ECHA

Methanol is a highly flammable liquid.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Methanol is readily biodegradable. It has a low adsorptive capacity to soils and is unlikely to bioaccumulate.

B. Biodegradation

Methanol is readily biodegradable. In a closed bottle test using seawater, there was 84% and 95% degradation after 10 and 20 days, respectively (Price et al., 1974; ECHA). [Kl. score = 2]

In a soil test using [^{14}C]-methanol, there was 53.4% degradation under aerobic conditions after 5 days, as measured by CO_2 evolution; and 46.3% degradation under anaerobic conditions after 5 days, as measured by CO_2 evolution (Scheunert et al., 1987; ECHA). [Kl. score = 2]

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

C. Environmental Distribution

The adsorption of methanol was investigated in three different soil types at 6°C (Lokke, 1984; ECHA). There was slight adsorption with the sandy soils tested (percentage organic matter of 0.09% and 0.1% in the samples) and with the clay soil (percentage organic matter was 0.22%). Methanol solutions of concentrations of 0.1, 1.0, 9 and 90 mg/L were used in one-hour exposure adsorption studies; the K_{oc} values were between 0.13 and 0.61 for all soil types and at all concentrations.

Based upon these K_{oc} values, if released to soil, methanol is expected to have very high mobility. If released into water, due to its high water solubility and low K_{oc}, methanol is not expected to adsorb to suspended solids and sediment in water.

D. Bioaccumulation

The BCF of methanol in *Cyprinus carpio* was determined to be 1.0 (Gluth et al. 1985); in *Leuciscus idus*, the BCF was < 10 (Hansch and Leo, 1985; Freitag et al. 1985). Therefore, the potential for bioaccumulation is low.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Methanol has low acute oral, dermal and inhalation toxicity in experimental animals but moderate to high acute oral and dermal toxicity in humans. Methanol is metabolised to formate, which is considered to be the ultimate toxicant in acute methanol intoxication in humans. Acute methanol toxicity in humans is characterised by CNS depression, followed by acidosis and ocular injury. Methanol is not irritating to the skin, but it is slightly irritating to the eyes. It is not a skin sensitiser. Repeated exposures by the oral and inhalation routes have not resulted in any systemic toxicity to rodents. In primates, adverse health effects on brain, kidney and heart were observed in chronic inhalation studies. Methanol is not genotoxic or carcinogenic. Conflicting results have been obtained concerning the effect of methanol on reproductive and developmental toxicity in experimental animals. However, it is not considered to have reproductive or developmental toxicity in humans.

B. Toxicokinetics and Metabolism

Several reviews on the metabolism and pharmacokinetics of methanol are available (Kavet and Nauss, 1990; Liesivuori and Savolainen, 1991; Tephly, 1991; IPCS, 1997; OECD, 2004a, b). Methanol is first oxidised to formaldehyde. This initial metabolic step involves different enzymes in rats than in primates and humans, although the rates are similar. A catalase–peroxidase system is primarily responsible for the initial step in rats, whereas alcohol dehydrogenase plays a major role in humans and monkeys. Methanol oxidation can also occur via hepatic microsomal oxidation involving the cytochrome P450 system.

Formaldehyde is converted to formic acid, which is converted to formate and a hydrogen ion. Conversion to formic acid is a two-step process, the second step is irreversible. In the first reaction, formaldehyde combines with reduced glutathione (GSH) to form S-formylglutathione. This is mediated by an NAD-dependent formaldehyde dehydrogenase. In the second reaction, thiolase catalyses the hydrolysis of S-formylglutathione to form formic acid and GSH. A folate-dependent pathway in the liver is responsible for formate metabolism in both rats and primates. Formate first forms a complex with tetrahydrofolate (THF) that is sequentially converted to 10-formyl-THF (by formyl-THF synthetase) and then to CO_2 (by formyl-THF dehydrogenase). THF is derived from folic acid in the diet and is also regenerated in the folate pathway. Although the folate pathway metabolises formate in both rats and monkeys, rats use the pathway more efficiently.

The dermal uptake rate of liquid methanol applied to the forearm of human volunteers was 11.5 mg/cm^2/hr (Dutkiewicz et al., 1980). The dermal flux for methanol in human skin (epidermis) *in vitro* is 8.29 mg/cm^2/hr (Schueplein and Blank, 1971). When 12 human volunteers immersed one hand into a vessel containing neat methanol for up to 16 minutes, the maximum methanol concentration in blood reached 1.9 ± 1.0 hr after exposure. Delivery rates from the skin into blood lagged exposure by 0.5 hours, and methanol continued to enter the blood for 4 hours following exposure. The average derived dermal absorption rate absorption rate was 8.1 $\pm$ 3.7 mg/cm^2/hr. The authors calculated that the maximum concentration of methanol in blood following immersion of one hand in methanol for approximately 20 minutes is comparable to that reached following inhalation exposures to 200 ppm methanol (Batterman and Franzblau, 1997).

C. Acute Toxicity

The acute oral LD_{50} for rats range from 6,200 to 13,000 mg/kg (Kimura et al., 1971; Welch and Slocum, 1943; Deichman and Mergard, 1948; Smyth et al., 1941). The acute dermal LD_{50} for rabbits was reported to be 20 mL/kg (Rowe and McCollister, 1982). The inhalation 4- and 6-hour LC_{50} values in rats are 128.2 and 87.5 mg/L, respectively (BASF, 1980a,b). Sublethal doses, however, produce CNS effects and ocular injury that may result in blindness. This effect has been seen in primates, but not in rodents, and has been attributed to the differences in blood levels of the metabolite, formic acid.

Methanol is metabolised to formate, which is considered to be the ultimate toxicant in acute methanol intoxication in humans. Acute methanol toxicity in humans is characterised by CNS depression, followed by acidosis and ocular injury. Generally, transient CNS effects appear above methanol levels of 200 mg/L and serious ocular symptoms appear above 500 mg/L (OECD, 2004a). This blood concentration can transiently be achieved in an adult person (70 kg) by ingestion of 0.4 mL methanol/kg (approximately 0.32 mg/kg). The minimal acute methanol dose to humans that can result in death is considered to be 300 to 1,000 mg/kg by ingestion, and fatalities have occurred in untreated patients with initial methanol blood levels in the range of 1,500-2,000 mg/L (OECD,

2004a). However, such high blood methanol levels able to cause death are not likely to be achieved through inhalation exposure.

D. Irritation

Methanol is not irritating to the skin of rabbits (BASF, 1975), but it is slightly irritating to the eyes of rabbits (BASF, 1975).

E. Sensitisation

Methanol was not considered a skin sensitiser to guinea pigs (BASF, 1979).

F. Repeated Dose Toxicity

Oral

Male and female Sprague–Dawley rats were dosed by oral gavage with 0, 100, 500 or 2,500 mg/kg of methanol for 90 days. There were no differences in body weight gain and food consumption between treated and control animals. Brain weights were decreased in both sexes in the 2,500 mg/kg dose group. Elevated serum glutamic pyruvate transaminase and alkaline phosphatase were noted in the 2,500 mg/kg dose group, but there were no adverse treatment-related effects in the gross pathology and histopathological evaluation. The NOAEL is 500 mg/kg/day (USEPA, 1986).

Sprague-Dawley rats were given in their drinking water 0, 500, 5,000 or 20,000 ppm methanol for 104 weeks, and then the animals were maintained until natural death. The study was conducted by the Ramazzini Foundation which uses its testing guideline for carcinogenicity studies and not an internationally accepted guideline. Treatment with methanol did not decrease survival. However, there was considerable early mortality; by 18 months, 30% of the male controls had died. In females, there were no differences in survival between controls and treated groups. There was still more early mortality in the females than expected, but it was less pronounced than the males. There was no obvious effect of methanol exposure on water consumption. The 20,000 ppm males and females weighed more than the controls (up to 14% and 7%, respectively) throughout the study. The 5,000 ppm females also weighed more (4%) than the controls at 24 months, but not at earlier time points. There were no body weight differences between the remaining treatment groups and the controls. The calculated methanol doses based on water intake were: 0, 55, 542 and 1,840 mg/kg/day for males; and 0, 67, 630 and 2,250 mg/kg/day for females. Nearly all rats in all dose groups had some pathology in the lung. The finding of lung pathology was consistent regardless of the age at death (not an old age response). The lung pathology included inflammation, dysplasia or tumours. Lung pathology was present in 70-100% of the first 10% of deaths in each group, including controls (70, 80, 80, 100% in males; and 90, 90, 100, 100% in females at 0, 500, 5,000 and 20,000 ppm, respectively). The degree of inflammation in the lungs is difficult to assess because no other lung information was recorded for the rats when a neoplasm in the lung was recorded (Soffritti et al., 2002; Cruzan, 2009; USEPA, 2013a) [Kl. score = 3].

Inhalation

Cynomolgus monkeys or Sprague–Dawley rats were exposed by inhalation to 0, 500, 2,000 or 5,000 ppm (0, 660, 2,620 or 6,552 mg/m^3) methanol for 6 h/day, 5 days/week for 4 weeks. There was no mortality and no clinical signs of toxicity among the monkeys, but there were a few signs of eye and nose irritation in the rats. No differences were seen between treated and control groups in body weight gain and organ weights, with the exception being decreased absolute adrenal weight in the 5,000 ppm female monkeys and increased relative spleen weights in the 2,000 ppm female rats.

These changes were not considered by the authors to be of biological significance. There were no treatment-related effects on the ophthalmoscopy, gross pathology or histopathology. The NOAEL for this study is 5,000 ppm (6,552 mg/m^3) (Andrews et al., 1987) [Kl. score = 4].

Groups of four male rats were exposed by inhalation to 0, 200, 2,000 or 10,000 ppm (0, 262, 2,621 or 13,104 mg/m^3) methanol for 6 hours/day, 5 days/week for 1, 2, 4 or 6 weeks. Additional groups of animals were exposed for 6 weeks followed by a 6-week recovery period. Evaluation of a number of parameters including lung weights, surfactant levels and enzyme activities did not reveal any adverse effects on the lung. No histopathological examinations were performed (White et al. 1983) [Kl score = 2].

Male and female F344 rats were exposed by inhalation to 0, 10, 100 or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 104 weeks. The average methanol doses were: 0, 3.7, 37 and 369 mg/kg/day in males; and 0, 5.9, 60 and 599 mg/kg/day for females. There were no treatment-related clinical signs and no effect on survival or food consumption. Lower body weights were seen in the 1,000 ppm females beginning around Day 259, but after Day 574, there was no difference from controls. Body weights in males were similar across all groups. There were no treatment-related effects on urinalysis, hematology or clinical biochemistry. Nor were there any treatment-related effects on organ weights or gross lesions. Histopathologic examination showed no statistically significant differences between treated and control animals (NEDO, 1985a) [Kl score = 2].

Male and female B6C3F1 mice were exposed by inhalation to 0, 10, 100 or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 78 weeks. The average methanol doses were: 0, 9.8, 95 and 947 mg/kg/day in males; and 0, 8.1, 106 and 1,071 mg/kg/day for females. There were no treatment-related clinical signs and no effect on survival or body weight. Food consumption was decreased slightly between months 7 and 12 in the 1,000 ppm females. Urinalysis, hematology and clinical biochemistry were similar across all groups. No differences were seen in organ weights, gross lesions or histopathology between treated and control mice (NEDO, 1985b) [Kl score = 2].

Dermal

No studies were identified.

G. Genotoxicity

In Vitro Studies

Methanol was not mutagenic to *Salmonella* strains TA97, TA98, TA100, TA1535, TA1537 and TA1538 in *in vitro* bacterial mutation assays with or without metabolic activation (De Flora et al., 1984a,b; Florin et al., 1980; Gocke et al.,1981). Equivocal results were obtained with *Salmonella* strain TA102 in the presence of metabolic activation (De Flora et al., 1984b). Methanol was not mutagenic in a DNA-repair test using various strains of *Escherichia coli* WP2 (De Flora et al., 1984a) and in a forward mutation assay using *Schizosaccharomyces pombe* (Abbondandolo et al., 1980).

Methanol did not induce micronuclei in Chinese hamster lung V79 cells in vitro (Lasne et al., 1984). Methanol was mutagenic in the mouse lymphoma assay in the presence of metabolic activation (McGregor et al., 1985), but it was not mutagenic in a Basc test or in a Drosophila, sex-linked, recessive lethal mutation assay (Gocke et al., 1981). Treatment of primary cultures of Syrian golden hamster embryo cells with methanol did not lead to cell transformation (Heidelberger et al., 1983).

In Vivo Studies

Male C57BL/6J mice were exposed by inhalation to 0, 800 or 4,000 ppm methanol, 6 hours/day for five days. There were no increased frequencies of micronuclei in blood cells; sister chromatid exchanges, chromosomal aberrations, or micronuclei in lung cells; or synaptosomal complex damage in spermatocytes (Campbell et al., 1991).

Normal or folate-deficient mice were given four daily intraperitoneal injections of up to 2,500 mg/kg of methanol. There was no increase in micronucleated erythrocytes in the treated mice compared to the controls (O'Loughlin et al., 1992).

Male and female NMRI mice were given a single intraperitoneal injection of 0, 1,920, 3,200 or 4,480 mg/kg methanol. There was no increase in micronuclei observed in the bone marrow at any dose level (Gocke et al., 1981).

H. Carcinogenicity

The carcinogenicity studies conducted on methanol were reviewed by Cruzan (2009) and by the USEPA (2013a).

Oral

Male and female SD rats were given in their drinking water 0, 500, 5,000 or 20,000 ppm methanol for 104 weeks. This study was conducted by the Ramazzini Foundation, which uses a unique methodology and not the standardised international testing guidelines. There was excessive early mortality, and lung pathology (inflammation, dysplasia, or tumours) was present in 87 to 94% of those dying anytime during the study. An increase in lympho-immunoblastic lymphomas was reported (Soffritti et al., 2002; Cruzan, 2009; USEPA, 2013a) [KI score = 3].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 10, 100 or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 104 weeks. The average methanol doses were: 0, 3.7, 37 and 369 mg/kg/day in males; and 0, 5.9, 60 and 599 mg/kg/day for females. There was no increase in tumours in the methanol-exposed rats and mice (NEDO, 1985a) [KI score = 2].

Male and female B6C3F1 mice were exposed by inhalation to 0, 10, 100 or 1,000 ppm methanol 19.5 hours/day, 7 days/week for 78 weeks. The average methanol doses were: 0, 9.8, 95 and 947 mg/kg/day in males; and 0, 8.1, 106 and 1,071 mg/kg/day for females. There was no increase in tumours in the methanol-exposed mice (NEDO, 1985b) [KI score = 2].

I. Reproductive and Developmental Toxicity

Based on the data available, methanol is not considered to have reproductive or developmental toxicity in humans (NICNAS, 2013).

The reproductive and developmental toxicity studies were reviewed by the NTP Centre for Evaluation of Risks to Human Reproduction (NTP-CERHR, 2003). Conflicting results have been obtained concerning the effect of methanol on testicular hormones in rats; nevertheless, methanol does not appear to be a male reproductive toxicant. The primate data indicates that methanol is unlikely to be a reproductive hazard in females. Methanol causes developmental effects at very high

exposure levels in both rats (≥ 10,000 ppm) and mice (≥ 2,000 ppm); there is also some evidence that it is a developmental neurotoxicant in rodents, but not in primates.

Blood methanol concentrations associated with serious teratogenic effects and reproductive toxicity are in the range associated with formate accumulation, which is likely to result in metabolic acidosis, and visual and clinical effects in humans (NTP-CERHR, 2003). Other effects (such as subtle, not yet definitive neurological effects observed in primates) may be exhibited at lower inhalation doses and lower methanol blood levels (OECD, 2004).

The limited data available in humans do not show an association of reproductive and developmental toxicity with methanol (NTP-CERHR, 2003). Based on the studies reviewed by the NTP (2003), it concluded that there is evidence to suggest that women with low folate levels may be more susceptible to the adverse developmental effects of methanol, but more information is necessary to clarify this issue (NICNAS, 2013).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for methanol follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

USEPA has derived an oral reference dose (RfD) by using exposure-response data from candidate principal inhalation studies of mice (Rogers et al., 1993) and rats (NEDO, 1987) and route-to-route extrapolation with the aid of the USEPA physiologically based pharmacokinetic (PBPK) model. The decision to use inhalation rather than oral study data is due to limitations in the database of oral studies, including the limited reporting of noncancer findings in the subchronic and chronic oral studies of rats, the determination that developmental effects are the most sensitive effects of methanol exposure. The RfD of 2 mg/kg/day was estimated from the Rogers et al. (1993) study for extra cervical rib incidence in mice (USEPA, 2013a). This RfD will be used for determining the drinking water guidance value.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD: Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2 L (ADWG, 2021)
Drinking water guidance value = (2 x 70 x 0.1)/2 = 7 mg/L

B. Cancer

Methanol was not carcinogenic to rats or mice in chronic inhalation studies. Increased tumours from methanol in drinking water were reported by Soffritti et al. (2002); however, there are methodological problems with this study and questions have been raised about the validity of the results. No cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Methanol is a highly flammable liquid.

Methanol does not exhibit the following physico-chemical properties:

- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Methanol exhibits a low toxicity concern for aquatic organisms, terrestrial invertebrates and plants.

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies conducted on methanol.

Table 2: Acute Aquatic Toxicity Studies on Methanol

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Bluegill	96-hour LC_{50}	15,400	1	Poirer et al. 1986
Salmo gairdneri	96-hour LC_{50}	20,100	1	Call et al., 1983
Pimphales promelas	96-hour LC_{50}	28,100	1	Call et al., 1983
Daphnia magna	96-hour EC_{50}	18,260	2	Dom et al., 2012; ECHA
Daphnia magna	48-hour EC_{50}	>10,000	2	Kuehn et al., 1989
Selenastrum capricornutum	96-hour EC_{50}	~22,000	2	Cho et al., 2008; ECHA
Chlorella pyrenoidosa	10 to 14-day EC_{50}	28,400	2	Stratton and Smith, 1988

Chronic Studies

No adequate chronic studies were identified. Reported studies were either invalid or their reliability was questionable. Methanol belongs to the category of organic chemicals exerting toxicity for aquatic organisms with a non-specific mode of action. The acute and chronic toxicity may be estimated for such kind of chemicals using QSAR methods. The ECOSAR model (version 1.11, US EPA, July 2012) predicts for methanol a chronic toxicity value of about 450 mg/L (equivalent to a NOEC) for *Pimephales promelas* and a value of 208 mg/L for *Daphnia magna* (REACH) [Kl. score = 1].

C. Terrestrial Toxicity

The terrestrial toxicity studies on methanol are listed in Table 3.

Table 3: Terrestrial Toxicity Studies on Methanol

Test Species (Method)	Endpoint	Results (mg/kg soil dw)	Klimisch score	Reference
Earthworm *Eisenia fetida* (OECD 222)	35-day EC_{50} 63-day EC_{50}	17,199 26,646	2	ECHA
Folsomia candida (OECD 232)	28-day EC_{25} 28-day NOEC* (reproduction)	2,842 1,000	1	ECHA
Hordeum vulgare (OECD 208)	14-day EC_{50} 14-day NOEC* (seedling emergence)	15,492 12,000	1	ECHA
	14-day EC_{25} 14-day NOEC* (shoot dry mass)	2,538 1,555		
	14-day EC_{25} 14-day NOEC* (root dry mass)	2,823 2,592		
	14-day EC_{25} 14-day NOEC* (shoot length)	4,885 2,592		
	14-day EC_{25} 14-day NOEC* (root length)	5,752 4,320		

* Since only EC_{25} values were available from the test results, NOECs were derived graphically from the representing treatment means.

D. Calculation of PNEC

The PNEC calculations for methanol follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (15,400 mg/L), *Daphnia* (> 10,000 mg/L) and algae (22,000 mg/L). There are no well-conducted long-term studies on methanol. Therefore, an assessment of 1,000 has been applied to the lowest reported effect concentration of 10,000 mg/L for *Daphnia*. The $PNEC_{water}$ is 10 mg/L.

PNEC sediment

There are no adequate toxicity studies on sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.3 mg/kg wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.81/1280) \times 1000 \times 10$
$= 6.3$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{soilid}]$
$= 0.8 + [0.2 \times 0.02/1000 \times 2400]$
$= 0.81\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= 0.61 \times 0.04$
$= 0.02$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for methanol is 0.61 L/kg.
f_{oc} = fraction of organic carbon suspended sediment = 0.04 [default].

PNEC soil

Experimental results from chronic studies are available for three trophic levels. The lowest NOEC is 1,000 mg/kg soil dry weight for the arthropod *Folsomia candida*. On the basis that the data consists of long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported long-term NOEC of 1,000 mg/kg soil dry weight. The $PNEC_{soil}$ is 100 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009 and ECHA, 2008).

Methanol is readily biodegradable and thus it does not meet the screening criteria for persistence.

Based on an experimental BCF of < 10 in fish, methanol does not meet the criteria for bioaccumulation.

There are no adequate chronic toxicity studies on methanol. Predicted toxicity based on QSAR methods indicates chronic values > 0.1 mg/L for fish and invertebrates. The acute EC_{50} values of methanol in fish, invertebrates and algae is >1 mg/L; thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that methanol is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Flammable Liquid Category 2

Acute Toxicity Category 3 [Oral]

Acute Toxicity Category 3 [dermal]

Acute Toxicity Category 3 [inhalation]

STOT SE Category 1 [optic nerve, central nervous system]

In the EU, there are concentration limits for the STOT SE classification of methanol. This may or may not apply to GHS classifications for Australian SDS.

Concentration range (%):

>10	STOT SE Category 1
>3 and <10	STOT SE Category 2

B. Labelling

Danger

C. Pictograms



The health hazard pictogram is omitted if the STOT SE classification for methanol does not apply (i.e., concentration of methanol is below the concentration limits).

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

Note: Methanol is used in the drilling mud product ALDACIDE® G ANTIMICROBIAL at a concentration of 0.1% to 1%. The safety and handling of methanol at this concentration in ALDACIDE® G ANTIMICROBIAL will be provided in the dossier on glutaraldehyde, the major constituent of ALDACIDE® G ANTIMICROBIAL.

<u>Occupational Exposure Standards</u>

The workplace exposure standard for methanol in Australia is 200 ppm (262 mg/m^3) as an 8-hour TWA and 250 ppm (328 mg/m^3) as a 15-minute STEL. There is also a skin notation indicating that absorption through the skin may be a significant source of exposure.

A. Transport Information

Methanol is used in drilling mud product ALDACIDE® G ANTIMICROBIAL at a concentration of 0.1 to 1%. The transportation information for ALDACIDE® G ANTIMICROBIAL will be provided in the dossier on glutaraldehyde, the major constituent of ALDACIDE® G ANTIMICROBIAL.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

Abbondandolo, A. et al. (1980). Mutat. Res. 79: 141 – 150.

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Andrews, L.S., Clary, J.J., Terrill, J.B., and Bolte, H.F. (1987). Subchronic inhalation toxicity of methanol. J. Toxicol. Environ. Health 20: 117-124.

BASF AG. (1975). Unpublished data, (XXIV 436), 03 July 1975; cited in OECD-SIDS SIAR on Methanol.

BASF AG. (1979). Unpublished data, (78/333), 11 April / 11 July 1979; cited in OECD-S SIDS SIAR on Methanol.

BASF AG. (1980a). Unpublished report, (80/158), 07 Aug. 1980; cited in OECD-SIDS SIAR on Methanol.

BASF AG. (1980b). Unpublished report, (80/158), 20 Nov. 1980; cited in OECD-SIDS SIAR on Methanol.

Batterman, S.A., and Franzblau, A. (1997). Time-resolved cutaneous absorption and permeation rates of methanol in human volunteers. Int. Arch. Occup. Environ. Health 70: 341-351.

Call, D.J., L.T. Brooke, N. Ahmad, J.E. Richter. (1983). Toxicity and metabolism studies with EPA priority pollutants and related chemicals in freshwater organisms, EPA-600/3-83-095, PB83-263665.

Campbell, J.A., Howard, D.R., Backer, L.C., Allen, J.W. (1991). Evidence that methanol does not induce chromosome damage in mice. Mutat. Res. 260 : 257-264.

Cho, C. W., Y-C. Jeon, T.P.T. Pham, K. Vijayaraghaven, Y-S. Yun. (2008). The ecotoxicity of ionic liquids and traditional organic solvents on microalga Selenastrum capricornutum. Ecotoxicol. Environ. Saf. 71: 166-171.

Cruzan, G. (2009). Assessment of the cancer potential of methanol. Crit. Rev. Toxicol. 39: 347-363.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Deichman, W.B., and Mergard, E.G. (1948). J. Ind. Hyg. Toxicol. 30: 373 – 378.

Dom, N., M. Penninck, D. Knapen, R. Blust. (2012). Discrepancies in the acute versus chronic toxicity of compounds with a designated narcotic mechanism. Chemosphere 87: 742-749.

Dutkiewicz, B., Korczalik, H., and Karwacki, W. (1980). Int. Arch. Occup. Environ. Health 47: 47: 81-88.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health RiskAssessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

De Flora, S., Zanacchi, A., Camoirano, A., Bennicelli, C. and Badolati, G.S. (1984a). Mutat. Res. 133(3) : 161 – 198.

De Flora, S., Zanacchi, A., Camoirano, A., Bennicelli, C. and Badolati, G.S. (1984b). Mutat. Res. 134 : 159 – 165.

Florin, I., Rutberg, L., Curvall, M. and Enzell, C.R (1980). Toxicol. 18 : 219 – 232.

Freitag, D., Lay, P. and Korte, F. (1985). Environmental Hazard Profile of Organic Chemicals: An experimental method for the assessment of the behaviour of organic chemicals in the ecosphere by means of simple laboratory tests with 14C labelled chemicals. Chemosphere, 14: 1589-1616.

Gluth, G., D. Freitag, W. Hanke, F. Korte. (1985). Accumulation of pollutants in fish. Comp. Biochem. Physiol., 81C: 273 – 277.

Gocke, E., M.-T. King, K. Eckhardt, D. Wild. (1981). Mutagenicity of cosmetic ingredients licensed by the European Communities. Mutat. Res. 90: 91 – 109.

Hansch, C. and Leo, A.J. (1985). Medchem. Project Issue No.26, Claremont CA, Pomona College.

Heidelberger, C. Freeman A., Pienta R.J., Sivak A., Bertram J.S., Casto B.C., Dunkel V., Francis M.W., Kakunaga T., Little J.B., Schechtman L.M. (1983). Mutat. Res. 114 : 283 – 385.

IPCS. (1997). Environmental Health Criteria on Methanol 196, WHO, Geneva.

Kavet , R., and Nauss, K.M. (1990). The toxicity of inhaled methanol vapors. CRC Crit. Rev. Toxicol. 20: 21 – 50.

Kimura, E.T., Ebert, D.M., and Dodge, P.W. (1971). Toxicol. Appl. Pharmacol. 19: 699 – 703.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Kuehn, R., et al. (1989). Water Research, 23: 495-499.

Lasne, C., et al. (1984.) Mutat. Res. 130: 273 – 282.

Liesivuori, J., and Savolainen, H. (1991). Pharmacol. Toxicol. 69: 157 – 163.

Lokke, H. (1984). Leaching of ethylene glycol and ethanol in subsoils. Water, Air, and Soil Pollution 22: 373-387.

McGregor, D.B et al. (1985). Environ. Mutagen. 7(Suppl. 3), A10.

NEDO. (1985a). 24-month inhalation carcinogenicity study on methanol in Fischer 344 rats (test no.: 5A-268), Report dated September 30, 1985, 10 volumes. Mitsubishi Kasei Institute for Toxicological and Environmental Sciences, Tokyo.

NEDO. (1985b). 18-month inhalation carcinogenicity study on methanol in B6C3F1 mice (test no.: 4A-223), Report dated March 30, 1985, 9 volumes. Mitsubishi Kasei Institute for Toxicological and Environmental Sciences, Tokyo.

NEDO. (1987). Toxicological research of methanol as a fuel for power station: summary report on tests with monkeys, rats and mice. Tokyo, Japan.

NICNAS. (2013). IMAP Single Assessment Report for Methanol: Human Health Tier II Assessment. May 17, 2013. Available at: https://www.industrialchemicals.gov.au/sites/default/files/Methanol_Human%20health%20tier%20II%20assessment.pdf

NTP-CERHR. (2003). NTP-CERHR Monograph on the Potential Human Reproductive and Developmental Effects of Methanol, Center for the Evaluation of Risks to Human Reproduction, National Toxicology Program, U.S. Department of Health and Human Services, NIH Publication, No. 03-4478.

OECD. (2004a). IUCLID Data Set for Methanol (CAS No. 67-56-1). Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=39B5D34A-2F5D-4D53-B000-E497B3A3EE89

OECD. (2004b). Screening Information Dataset (SIDS) Initial Assessment Report for Methanol (CAS No. 67-56-1). Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=39B5D34A-2F5D-4D53-B000-E497B3A3EE89

O'Loughlin, K. et al. (1992). Environ. Mutagen Soc. 47 (Abstr.).

Poirer S.H., Knuth, L.M., Anderson-Buchou, C.D,. et al. (1986). Comparative toxicity of methanol and N,N-dimethylformamide to freshwater fish. Bull. Environ. Contam. Toxicol., 37: 615-621.

Price, K.S., G.T. Waggy, R.A. Conway. (1974). Brine shrimp bioassay and seawater BOD of petrochemicals. J. Water Pollution Control Fed. 46: 63-77.

Rogers, JM; Mole, ML; Chernoff, N; Barbee, BD; Turner, CI; Logsdon, TR; Kavlock, RJ. (1993). The developmental toxicity of inhaled methanol in the CD-1 mouse, with quantitative dose-response modeling for estimation of benchmark doses. Teratology 47: 175-188. http://dx.doi.org/10.1002/tera.1420470302.

Rowe, K., and McCollister, S.B. (1982). In: Patty's Industrial Hygiene and Toxicology, 3rd rev. ed. (G. D. Clayton and F. E. Clayton, eds.), pp. 4527-4708, Wiley, New York.

Scheunert, I., D. Vockel, J. Schmitzer, F. Korte. (1987). Biomineralization rates of 14C-labelled organic chemicals in aerobic and anaerobic suspended soil. Chemosphere 16: 1031-1041.

Schuelplein, R.J., and Blank, I.H. (1971). Physiol. Rev. 51: 702-747.

Smyth, H.F., Seaton, J., and Fisher, L. (1941). J. Ind. Hyg. Toxicol. 23: 259 – 268.

Soffritti, M., Belpoggi, F., Cevolani, D., Guarino, M., Padovani, M., and Maltoni, C. (2002). Results of long-term experimental studies on the carcinogenicity of methyl alcohol and ethyl alcohol in rats. In: M.A. Mehlman (Ed.), Carcinogenesis bioassays and protecting public health: commemorating the lifework of Cesare Maltoni and colleagues, pp. 46-69, Bologna, Italy: Ann. N.Y. Acad. Sci.

Stratton, G.W., and Smith, T.M. (1988). Interaction of organic solvents with the green alga Chlorella pyrenoidosa, Bull. Environ. Contam. Toxicol., 40: 736-742.

Tephly, T.R. (1991). The toxicity of methanol. Life Sci. 48: 1031 – 1041.

USEPA. (1986). Rat Oral Subchronic Study on Methanol, U.S. Environmental Protection Agency, Washington, DC. Cited in the U.S. Integrated Risk Information System (IRIS) database for methanol (https://www.epa.gov/iris).

USEPA. (2013a). Toxicological Review of Methanol (Noncancer) (CAS No. 67-56-1) in Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-11/00FA U.S. Environmental Protection Agency, Washington, DC. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0305tr.pdf

USEPA. (2013b). Integrated Risk Information System (IRIS) Chemical Assessment Summary: Methanol (CASRN 67-56-1). Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0305_summary.pdf

Welch, H., and Slocum, G.G. (1943). J. Lab. Chem. Med. 28: 1440.

White, L.R., Marthinsen, A.B.L., Ricchard, R.J., Eik-Nes, K.B., and Nilsen, O.G. (1983). Biochemical and cytological studies of rat lung after inhalation of methanol vapor. Toxicol. Lett. 17: 1-5.

ETHYLENE DIAMINETETRAACETIC ACID TETRASODIUM SALT [NA_4EDTA]

This dossier on ethylene diaminetetraacetic acid tetrasodium salt (Na_4EDTA) presents the most critical studies pertinent to the risk assessment of Na_4EDTA in its use in coal seam gas extraction activities It does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the EU Risk Assessment Report on Na_4EDTA, and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Tetrasodium{[2-bis-carboxymethyl-amino)-ethyl]-carboxymethyl-amino}-acetate

CAS RN: 64-02-8

Molecular formula: $C_{10}H_{12}N_2O_8Na_4$

Molecular weight: 380.2 g/mol

Synonyms: Tetrasodium ethylenediaminetetraacetate; ethylenediaminetetraacetic acid tetrasodium salt; ethylene dinitrilotetraacetic tetrasodium salt; Edetic acid tetrasodium salt; Na_4EDTA or Na_4EDTA tetrasodium; Edetate sodium or Sodium ededate; N,N'-1,2-Ethanediylbis[N-(carboxymethyl)glycine]tetrasodium salt; tetrasodium 2,2',2'',2'''-(ethane-1,2-diyldinitrilo)tetraacetate

SMILES: C(CN(CC(=O)[O-])CC(=O)[O-])N(CC(=O)[O-])CC(=O)[O-].[Na+].[Na+].[Na+].[Na+]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Na_4EDTA

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White powder	2	ECHA
Melting Point	> 150°C; > 300°C; decomposition may occur at > 150°C (pressure not provided)	2	ECHA
Boiling Point	-	-	-
Density	1670 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	-	-	-
Partition Coefficient (log K_{ow})	-	-	-
Water Solubility	500 g/L @ 20°C	2	ECHA
Auto flammability	> 200 °C @ 101.3 kPa	2	ECHA

The most important property of Na_4EDTA is that it forms complexes (usually 1:1-complexes) with multivalent metal ions (EU, 2004).

III. ENVIRONMENTAL FATE SUMMARY

A. Summary

Na_4EDTA is not readily biodegradable, but it can under certain conditions (i.e., alkaline pH), which is realistic under environmental surface water conditions, be degraded. Therefore, it can be concluded that EDTA is ultimately biodegradable under such environmental conditions (REACH). It is not expected to adsorb to soil or sediment. Na_4EDTA has a low potential for bioaccumulation.

B. Partitioning

Na_4EDTA is typically released to the environment in its complexed form (Nowack et al., 2001). The speciation of metal complexes is determined by the complex released, and metal exchange reactions mediated by its interactions with the chemistry of the receiving water compartment (Nowack, 2002; EU, 2004). However, complexes of Na_4EDTA with iron(III) are often detected in river water due to the ubiquity of iron(III) and the slow kinetics of relevant metal exchange reactions (half-life approximately 20 days) (Nowack, 2002).

Partitioning of complexed EDTA between water and sediment compartments is dependent on the metal ion complexed. For example, EDTA complexed with cobalt(III) and iron(III) partitions predominately to the water compartment, while lead(II) EDTA complexes adsorb strongly to sediment (Nowack, 2002).

Na_4EDTA is resistant to hydrolysis. However, EDTA is photolytically unstable when complexed with iron(III) ions. The complex is reported to have a half-life of 5 hours in central Europe in summer, with a worst-case half-life of 20 days (EU, 2004).

C. Biodegradation

There have been many degradation tests conducted on Na_4EDTA; in most cases, the acid or the sodium salt was tested, but not Na_4EDTA in its complexed form. Na_4EDTA is not readily biodegradable (EU, 2004). In a 28-day Sturm test, there was only 10% degradation (measured as CO_2) after 28 days (EU, 2004). In a Closed Bottle test, degradation was 3% and 0% of TOD after 28 days in two separate tests (EU, 2004). Inherent biodegradability tests have shown variable results, ranging from 0 to 37% biodegradation rates (EU, 2004). If a chemical is found to be not readily or inherently biodegradable, it is categorised as Persistent since its half-life is greater than 60 days (DoEE, 2017).

Na_4EDTA can be degraded under alkaline conditions. A Closed Bottle test was conducted to investigate the potential of samples from a river, a ditch and a lake to degrade $CaNa_2EDTA$ (8 mg/L) at pH values 6.5 – 8.0. There was little to no biodegradation (2-12%) at pH 6.5 within the first 28 days and 60-83% after 49 days. At pH 8, rates of 53, 62 and 72% were seen after 28 days and 75-89% after 35 days (van Ginkel et al., 1999). The pH values of lakes and river water range from 7.7 to 8.5; however, Na_4EDTA is preferably complexed with heavy metal ions (EU, 2004).

Na_4EDTA can be biodegraded in soil under aerobic conditions. After four weeks, biodegradation of Na_4EDTA between 4.8 and 7.9% at 30°C was determined in agriculture soil of mid-Michigan (EU, 2004). Another study showed primary degradation of 53 to 60% after 173 days at 22°C. An additional 39% of the substance was assumed to be eliminated by sorption and abiotic degradation (EU, 2004).

D. Environmental Distribution

Environmental transport of Na_4EDTA will be determined by the metal ions it is complexed with. Most studies investigating the transport of Na_4EDTA complexes compare this to transport of the uncomplexed metal. Generally, Na_4EDTA is found to decrease adsorption of metals and therefore increase its potential for transport in the environment. For instance, the mobility of Na_4EDTA in soil was investigated by eluting solutions of H_4EDTA and ZnEDTA through cores of two various surface soils. H_4EDTA was slightly adsorbed and moved quite readily through both soils. The Na_4EDTA from ZnEDTA also moved readily through the soils (EU, 2004). Therefore, due to the ionic structure of Na_4EDTA, no adsorption to the organic fraction of soils is expected under environmental relevant pH conditions and the substance is expected to be mobile.

If released to water, Na_4EDTA will not evaporate from the water surface into the atmosphere and, based on its high water solubility value and ionic structure noted above, is likely to remain in water and not adsorb to sediment.

E. Bioaccumulation

BCF values of 1.8 (0.08 mg/L Na_4EDTA) and 1.1 (0.76 mg/L Na_4EDTA) were determined in a 28-day bioaccumulation test on *Lepomis macrochirus* (EU, 2004). These measured values indicate a low potential for bioaccumulation.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Na_4EDTA exhibits low acute toxicity by the oral route. It is irritating to the eyes. Data on other sodium salts of EDTA show that these substances are not skin sensitizers. Exposures of sodium EDTA salts to rats in their diet for up to two years showed no systemic effects. No systemic effects were seen in rats exposed by inhalation to a sodium EDTA salt for 13 weeks, although there were some localised (site-of-contact) effects seen in the respiratory tract. Sodium EDTA salts are not considered to be genotoxic or carcinogenic. It is not a reproductive or developmental toxicant.

B. Acute Toxicity

Oral

For Na_4EDTA, the oral LD_{50} values in rats from three different studies range from 1,700 to 1,913 mg/kg; two additional limit studies reported the oral LD_{50} values to be > 2,000 mg/kg (EU, 2004).

Inhalation

No acute inhalation studies have been conducted on Na_4EDTA. In a study on Na_2EDTA (CAS No. 139-33-3), male Wistar rats were exposed nose-only to an aerosol of 0, 30, 300 or 1,000 mg/m^3 for 6 hours on five consecutive days. Exposure to 1,000 mg/m^3 for one day (6 hours) resulted in deaths of 6 out of 20 animals (ECHA) [KI score = 1].

Dermal

No dermal toxicity studies on Na_4EDTA are available.

C. Irritation

Application of 0.5 g (in 80% water) of Na_2EDTA to the skin of rabbits for 4 hours under occlusive conditions was not irritating. The mean of the 24, 48, and 72-hour erythema scores was 0.4. The mean of the 24, 48, and 72-hour oedema scores was 0 (ECHA) [KI score = 1]. Application of a 40% solution of Na_4EDTA in water (CAS No. 67401-50-7) with a pH 11 to the skin of rabbits for up to 20 hours under occlusive conditions was not irritating (ECHA) [KI score = 2].

Instillation of 50 mg of Na_4EDTA into the eyes of rabbits was irritating. The mean 24 and 72-hour scores were: 1.25 for corneal lesions; 1.75 for conjunctival redness; 1.25 for chemosis; and 0 for iridial lesions (ECHA) [KI score = 2].

D. Sensitisation

No sensitization studies have been conducted on Na_4EDTA. Na_3EDTA was not a dermal sensitizer in a guinea pig sensitization study (ECHA) [KI score = 2].

Na_2EDTA was not a dermal sensitizer in a guinea pig maximisation test. The intradermal injection was 0.5% in corn oil; the topical applications were 30% in corn oil, and the challenge dose was 30% in corn oil (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

Male Holtzman rats were fed in their diet 0, 1, 5, or 10% (0, 500, 2,500 or 5,000 mg/kg/day) Na_2EDTA for 90 days. There was mortality in the mid- and high-dose groups: 20% and 60%, respectively. Body weights and food consumption were significantly lower in the mid- and high-dose groups compared to controls. The animals in these two groups also had diarrhea and were emaciated, and water consumption was increased. The 10% group showed intermittent decreases in hematocrit and haemoglobin levels, and the livers appeared pale when examined at necropsy. Histopathologic evaluation showed no treatment-related effects. The NOAEL is 500 mg/kg/day (Wynn et al., 1970; ECHA) [KI score = 2].

Male and female F344 rats were fed in their diet 0, 3,750 or 7,500 ppm (0, 248 or 495 mg/kg/day) Na_3EDTA. There were no clinical signs; survival and body weights were similar between treated and control groups throughout the study. There was no evidence of adverse effects in the gross necropsy and histopathologic examinations. The NOAEL is 495 mg/kg/day (EU, 2004) [KI score = 2].

Male and female B6C3F1 mice were fed in their diet 0, 3,750 or 7,500 ppm (0, 469 or 938 mg/kg/day) Na_3EDTA. There was no clinical signs and survival was similar across all groups. Body weights in the high-dose males showed a significant decrease in body weights throughout the study. There was no evidence of adverse effects in the gross necropsy and histopathologic examinations. The NOAEL is 938 mg/kg/day (NCI, 1977) [KI score = 2].

Inhalation

Male and female Wistar rats were exposed nose-only to 0, 0.5, 3 or 15 mg/m^3 Na_2EDTA (as an aerosol dust) 6 hours/day, 5 days/week for 13 weeks. The MMAD of the particles for the respective groups were: 2.3 - 2.8 µm, 2.0 – 2.4 µm and 2.3 – 2.5 µm, respectively. There were no clinical signs of toxicity or any effects on the haematology and clinical chemistry parameters. Histopathological examination showed some effects on the larynx in the 15 mg/m^3 females, but no evidence of

systemic toxicity. The NOAEC for systemic toxicity in this study is 15 mg/m^3. The NOAEC for localized (site-of-contact) effects is 3 mg/m^3 (ECHA) [KI score = 1].

Dermal

No dermal studies are available.

F. Genotoxicity

In Vitro Studies

There are no *in vitro* genotoxicity studies on Na_4EDTA; however, studies have been conducted on Na_2EDTA and Na_3EDTA (Table 2).

Table 2: In Vitro Genotoxicity Studies on Na_2EDTA and Na_3EDTA

Test System	Test Substance	Results*		Klimisch Score	Reference
		-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* and *E. coli* strains)	Na_3EDTA	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	Na_2EDTA	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	Na_3EDTA	-	-	2	ECHA
Chromosomal aberration (CHO cells)	Na_3EDTA	-	-	2	ECHA
Cell transformation assay (Syrian hamster embryos)	Na_2EDTA	N/A	-	1	ECHA
Cell transformation assay (Syrian hamster embryos)	Na_3EDTA	N/A	-	2	ECHA

*+, positive; -, negative; N/A, not applicable.

In Vivo Studies

There are no *in vivo* genotoxicity studies on Na_4EDTA. Studies conducted on other sodium salts of EDTA are summarised below.

Male NMRI mice were dosed by oral gavage with 0, 500, 1,000 or 2,000 mg/kg Na_2EDTA once daily for two consecutive days. There were no increased frequencies of micronuclei in the normochromatic erythrocytes of the bone marrow in the treated animals compared to controls (ECHA) [KI score = 1].

Male Balb/c mice were given a single intraperitoneal injection of 0, 93 or 186 mg/kg Na_2EDTA and the spermatocytes were examined 6 hours and 5 days later for aneuploidy. There were no significant increases in aneuploidy in the primary and secondary spermatocytes at both time points (Zordan et al., 1990; ECHA) [KI score = 2].

Male Balb/c mice were given a single intraperitoneal injection of 0 or 186 mg/kg Na_2EDTA, and the frequency of micronuclei was analysed in the Golgi and Cap phase, which represents the two earliest phases of spermatid development. The sampling time points were 24 and 48 hours post-dosing.

Micronuclei were induced in the Golgi phase spermatids at both time points; there was no increase in micronuclei in the Cap phase (Russo and Lewis, 1992; ECHA) [KI score = 2].

No chromosomal aberrations were noted in male Balb/c mouse spermatogonia following a single intraperitoneal dose of 186 mg/kg Na_2EDTA (Russo and Lewis, 1992; ECHA) [KI score = 2].

In summary, Na_2EDTA did not induce genotoxicity in bone marrow cells in mice. In germ cells of mice, Na_2EDTA did not induce chromosomal aberrations in spermatogonia, aneuploidy in primary and secondary spermatocytes, but micronuclei were induced at a specific phase of spermatogenesis. The dose of Na_2EDTA used to induce micronuclei in these spermatids is an extremely high dose; given that the induction of aneuploidy is based on a threshold mode-of-action, it is unlikely that this effect will occur in humans exposed to sodium salts of EDTA. Overall, the sodium salts of EDTA are not genotoxic (EU, 2004).

G. Carcinogenicity

Oral

No studies are available on Na_4EDTA.

Male and female F344 rats were fed in their diet 0, 3,750 or 7,500 ppm (0, 248 or 495 mg/kg/day) Na_3EDTA. There were no clinical signs; survival and body weights were similar between treated and control groups throughout the study. Tumour incidences were similar across all groups, indicating no evidence of carcinogenicity from chronic exposure to Na_3EDTA (NCI, 1977) [KI score = 2].

Male and female B6C3F1 mice were fed in their diet 0, 3,750 or 7,500 ppm (0, 469 or 938 mg/kg/day) Na_3EDTA. There was no clinical signs and survival was similar across all groups. Body weights in the high-dose males showed a significant decrease in body weights throughout the study. Tumour incidences were similar across all groups, indicating no evidence of carcinogenicity from chronic exposure to Na3EDTA (NCI, 1977) [KI score = 2].

No inhalation or dermal carcinogenicity studies were located.

H. Reproductive Toxicity

No studies are available on Na_4EDTA.

Male and female Wistar rats were given in their feed 0, 50, 125 or 250 mg/kg/day CaNa2EDTA (CAS No. 62-33-9) for two years. The study included reproductive and lactation components in four successive generations. There were no significant differences between treated and controls groups in behaviour, clinical signs, survival, body weight gain in any generation. The high-dose group showed no treatment-related organ weight changes or histopathologic effects in any of the organs examined, including the testes. There were no consistent treatment-related effects on reproductive performance or developmental effects in any of the four generations examined. The NOAEL for reproductive toxicity is 250 mg/kg/day, the highest dose tested (Oser et al., 1963; ECHA) [KI score = 2].

I. Developmental Toxicity

Pregnant female rats were dosed by oral gavage with 0 or 1,000 mg EDTA/kg during GD 7-14. The salts of EDTA (Na_2EDTA, Na_3EDTA, $CaNa_2EDTA$ and Na_4EDTA were also included in this study and were tested on an equimolar basis. For Na_4EDTA, the dose is 1,374 mg/kg/day which was given as

equally divided doses twice daily. There was diarrhea in 90% of the dams after each daily dosing and which disappeared after the last day of dosing. There was also reduced feed intake and reduced weight gain during the treatment period; both recovered during the post-treatment period. There was no developmental toxicity in any of the treatment groups compared to controls. The NOAEL for maternal and developmental toxicity for Na_4EDTA is 1,374 mg/kg/day (Schardein et al. 1981; ECHA).

The toxicity and teratogenicity of Na_2EDTA were studied in pregnant female CD rats following different routes of administration during GD 7-14. When Na_2EDTA was administered in the diet at 3% (average dose of 954 EDTA/kg/day), the dams had reduced feed intake, severe diarrhea and severe weight loss. There was a significant proportion of foetal deaths (~33% resorptions/litter), significantly lower average foetal weight and gross external, internal and skeletal malformations in about 71% of the surviving foetuses. When Na_2EDTA was administered by oral gavage at doses of 1,250 or 1,500 mg EDTA/kg/day, there was severe toxicity to the dams: 3/8 and 7/8 deaths in the 1,250 and 1,500 mg/kg/day groups, respectively; significantly reduced weight gain and diarrhea in the 1,250 mg/kg/day group. There was a significantly higher proportion of malformed surviving foetuses. When administered subcutaneously with 375 mg EDTA, the dams showed signs of severe pain (vocalisations and shock) and 24% of them died; there was also a significant reduction in body weight and feed intake. Foetal toxicity included about 32% resorptions/litter and significant reduction of foetal body weight, and about a 4% malformed survivors/litter (Kimmel, 1977; ECHA).

Pregnant female CD rats were given in their diet 0, 2, or 3% Na_2EDTA; in addition, a group was fed 3% Na_2EDTA supplemented with 1,000 ppm zinc (Zn). Exposures were as follows: 2% (GD 0-21), 3% (GD 0-21, GD 6-14, or GD 6 to 21); 3% + Zn (GD 6-21). The dietary doses of 2% and 3% Na_2EDTA correspond to approximately 1,000 and 1,500 mg/kg/day, respectively. All of the dams had moderate to severe diarrhea. In the 2% Na_2EDTA group, all rats had living young at term; the litter size was normal; the young were slightly small than controls, and 7% of the foetuses were malformed. In the 3% Na_2EDTA (GD 0-21), reproduction was severely disturbed, and none of the females had grossly visible implantation sites. In the 3% Na_2EDTA (GD 6-14 and 6-21), almost all females had implantation sites; half of the sites had dead or resorbed foetuses; 100% of the foetuses were malformed in the GD 6-21 group. In the 3% Na_2EDTA + Zn group, there was a normal reproduction, and none of the young was malformed. It was suggested by the study authors that the congenital abnormalities caused by EDTA were due specifically to zinc deficiency (Swenerton et al., 1977).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived for Na_4EDTA.

The Australian drinking water guidance value for EDTA is 0.25 mg/L (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Na_4EDTA does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidizing potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Details on the aquatic toxicity studies on Na_4EDTA and its sodium salts can be found in the EU Risk Assessment Report (RAR) on Na_4EDTA (EU, 2004). The mode-of-action of Na_4EDTA in aquatic systems involves disturbances of metal metabolism; hence, the complex formation properties of Na_4EDTA need to be taken into account. In general, complexed and non-complexed EDTA have a low toxicity concern for fish and invertebrates. EDTA is highly toxic to algae in tests using standard media; the effect is probably caused by nutritional deficiency. If nutrient metal concentrations are increased, then EDTA has a low toxicity concern for algae; this is the more likely scenario in the environment.

B. Aquatic Toxicity

Uncomplexed Na_4EDTA will only be present in the test media of aquatic toxicity studies when present in an excess amount relative to the calcium and magnesium ions, as well as some level of heavy metal ions, which are present mainly as trace nutrients. Complexes with the heavy metals are predominant because the formation constants are several orders of magnitude higher than those of the calcium and magnesium ions. After addition of Na_4EDTA (as an acid or sodium salt), the concentration of uncomplexed trace metals will decrease considerably, and if there is a surplus of Na_4EDTA, there will also be complexing with the calcium and magnesium ions.

Na_4EDTA and its sodium salts appear to be more toxic in an uncomplexed form in the acute toxicity studies. Most of the acute fish studies have LC_{50} values that are much greater than 100 mg/L, with the exception of two studies tested with H_4EDTA in soft and very soft water: the LC_{50} values were 41 and 59.8 mg/L, respectively. It is thought that there was an excess of uncomplexed Na_4EDTA in the test media of these two studies due to the low levels of magnesium and calcium ions in soft water; this, however, is an unlikely scenario in the environment.

The EU RAR (EU, 2004) considered the most relevant chronic fish toxicity study to be an early-life stage test on zebrafish; the NOEC was > 26.8 mg/L H_4EDTA ($CaNa_2EDTA$ was the test substance) (EU, 2004).

The acute toxicity tests on *Daphna magna* reported 24-hour EC_{50} values of 480 to 790 mg/L (EU, 2004). The 21-day NOEC from a *Daphnia* reproduction test was 22 mg/L (EU, 2004).

Essential trace metal bioavailability seems to be the critical factor in algal toxicity from Na_4EDTA exposure. The ratio of the Na_4EDTA concentration to the metal cations is a critical element to algal growth and not the absolute Na_4EDTA concentration. H_4EDTA concentrations up to 310 mg/L will not cause any effect on algal growth if there is sufficient trace metals present. Since there is a considerable amount of metal ions present in the environment, Na_4EDTA is not expected to have an intrinsic toxic effect on plants. In a study with *Scenedesmus subspicatus*, an EC_{10} value of 0.37 mg/L was obtained (EU, 2004). The EU RAR considered that the effect was probably due to nutrient deficiency because essential metals (Cu, Zn, Co) are largely complexed to the Na_4EDTA, resulting in considerably reduced concentrations. In another study with *Pseudokirchnerella subcapitata* conducted according to OECD TG 201, the ECb_{50} and ECr_{50} of Fe(III)EDTA were > 100 mg/L; the NOEC values were 79.4 and 48.4 mg/L, respectively, when based on mean measured concentrations.

C. Terrestrial Toxicity

No relevant studies are available. The only test results that are available are those that have investigated the decrease of heavy metal toxicity caused by Na_4EDTA.

D. Calculation of PNEC

The PNEC calculations for Na_4EDTA follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 22 mg/L for algae (EU, 2004). On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported long-term NOEC of 22 mg/L for invertebrates. The $PNEC_{water}$ is 2.2 mg/L.

PNEC sediment

No experimental toxicity data on sediment organisms are available. The equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$ because Na_4EDTA is not expected to adsorb to sediment. The assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No experimental toxicity data on soil organisms are available. The equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$ because Na_4EDTA is not expected to adsorb to soil. The assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Na_4EDTA is not readily biodegradable; thus, it meets the screening criteria for persistence.

The experimental BCF of Na_4EDTA in fish is 1.1 – 1.8. Thus, Na_4EDTA does not meet the criteria for bioaccumulation.

The lowest NOEC from chronic aquatic toxicity studies is > 0.1 mg/L. Na_4EDTA and its sodium salts appear to be more toxic in an uncomplexed form in the acute toxicity studies. Acute EC_{50} values in fish, invertebrates and algae are > 1 mg/L. Thus, Na_4EDTA does not meet the screening criteria for toxicity.

The overall conclusion is that Na_4EDTA is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Acute Toxicity Category 4 [oral]

Acute Toxicity Category 4 [inhalation]

Eye Damage Category 1

B. Signal Word

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon monoxide, carbon dioxide, nitrogen oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical protective clothing.

C. Accidental Release Measures

Personal Precautions

Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eye, and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessarily provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust. Take precautionary measures against static discharges by bonding and grounding equipment.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for Na_4EDTA.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Na_4EDTA is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

EU. (2004). European Union Risk Assessment Report for Tetrasodium ethylenediamineacetate (CAS No. 64-02-8), Volume 51. Available at: https://echa.europa.eu/documents/10162/415c121b-12cd-40a2-bd56-812c57c303ce

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Kimmel, C.A. (1977). Effect of route of administration on the toxicity and teratogenicity of EDTA in the rat. Toxicol. Appl. Pharmacol. 40: 299-306.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

National Cancer Institute [NCI]. (1977). Bioassay of Trisodium Ethylenediamininetetraacetate trihydrate (EDTA) for Possible Carcinogenicity (CAS No. 150-38-9). NCI-CG-TR-11, DHEW Publication No. (NIH) 77-811. U.S. Department of Health, Education, and Welfare, Public Health Service, National Institutes of Health.

Nowack, B. (2002). 'Environmental chemistry of aminopolycarboxylate chelating agents', Environmental Science and Technology, vol. 36(19), pp. 4009-4016.

Nowack, B., Kari, F.G., Krüger, H.G. (2001)., 'The remobilization of metals from iron oxides and sediments by metal-EDTA complexes', Water, Air and Soil Pollution, vol. 125, pp. 243-257.

Oser, B.L., Oser, M., and Spencer, H.C. (1963). Safety evaluation studies of calcium EDTA. Toxicol. Appl. Pharmacol. 5: 142-162.

Russo, A., and Levis, A.G. (1992). Further evidence for the aneuploidogenic properties of chelating agents: Induction of micronuclei in mouse male germ cells by EDTA. Environ. Mol. Mutagen. 19: 125-131.

Schardein, J.L., Sakowski, R., Petrere, J., and Humphrey, R.R. (1981). Teratogenesis studies with EDTA and its salts in rats. Toxicol. Appl. Pharmacol. 61: 423-428.

Swenerton, H., and Hurley, L.S. (1971). Teratogenic effects of a chelating agent and their prevention by zinc. Science 173: 62-64.

van Ginkel C.G., Kester H., Stroo C.A., van Haperen A.M. (1999). Biodegradation of EDTA in pulp and paper mill effiuent by activated sludge. Appl Water Sci 8:111 (1999)

Wynn, J.E., van Riet, B., and Borcelleca, J.F. (1970). The toxicity and pharmacodynamics of EDTA: Oral administration to rats and comparison with EDTA. Toxicol. Appl. Pharmacol. 16: 807-817.

Zordan, M., Russo, A., Costa, R., Bianco, N., Beltrame, C., and Levis, A.G. (1990). A concerted approach to the study of the aneuoploidogenic properties of two chelating agents (EDTA and NTA) in the germ and somatic cell lines of Drosophila and the mouse. Environ. Mutagen. 15: 205-213.

POLY(OXY-1,2-ETHANEDIYL), ALPHAHEXYL-OMEGA-HYDROXY-
(ETHYLENE GLYCOL-N-MONOHEXYL ETHER)

This dossier on poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy or ethylene glycol-n-monohexyl ether (EGMHE) does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies pertinent to the risk assessment of EGMHE in its use in in coal seam gas extraction activities. The majority of information presented in this dossier was obtained from the OECD-SIDS documents on a well-defined surrogate ethylene glycol monobutyl ether (EGBE) (CAS RN 111-76-2), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): 2-hexoxyethanol

CAS RN: 31726-34-8

Molecular formula: $C_8H_{18}O_2$

Molecular weight: 146.23 g/mol

Synonyms: Poly(oxy-1,2-ethanediyl), alpha-hexyl-omega-hydroxy-; ethylene glycol monohexyl ether; EGHE; alpha-Hexyl,omega-hydroxypoly(oxy-1,2-ethanediyl); hexyl alcohol, ethoxylated

SMILES: CCCCCCOCCO

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of EGBE (CAS No. 111-76-2)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	A colourless liquid. Odour is mild, ether-like, and slightly rancid.	2	ECHA
Melting Point	-74.8°C @ 101.3 kPa	2	ECHA
Boiling Point	171 – 171.5°C @ 101.3 kPa	2	ECHA
Density	900 kg/m^3 @ 20°C	2	ECHA
Vapour Pressure	80 Pa @ 20°C	2	ECHA
Partition Coefficient (log K_{ow})	0.81 (temperature not available)	1	ECHA
Water Solubility	900 g/L @ 20°C (fully soluble)	2	ECHA
Flash Point	67°C	2	ECHA
Auto flammability	230°C	2	ECHA
Viscosity	3.642 mm^2/s (3.28 mPa.s)	2	ECHA
Henry's Law Constant	0.041 Pa.m^3/mol	2	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

EGBE is readily biodegradable. It is not expected to bioaccumulate. EGBE has a low tendency to bind to soil or sediment.

B. Biodegradation

EGBE was considered readily biodegradable in an OECD 301B test. Degradation was 90.4% after 28 days; the 10-day window was met (ECHA) [KI score = 2]. Results from another OECD 301B test showed 63% and 74-75% degradation after 10 and 28 days, respectively (ECHA) [KI score = 2]. An OECD 301 D test showed 67-75% degradation after 15 days and 73-77% after 28 days (ECHA) [KI score = 2]. In a Zahn-Wellen (OECD 302B test), degradation of EGBE was 95% after 8 days, measured as DOC removal (ECHA) [KI score = 2].

C. Environmental Distribution

No experimental data are available for EGBE. Using KOCWIN in EPI Suite™ (U.S. EPA, 2017), the estimated K_{oc} value from log K_{ow} is 7.624 L/kg. The estimated K_{oc} value from the molecular connectivity index (MCI) is 2.823 L/kg.

D. Bioaccumulation

No bioconcentration studies have been conducted on EGBE. EGBE is not expected to bioaccumulate based on the experimental log K_{ow} of 0.81 (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

EGBE has low-to-moderate acute toxicity by the oral route. Species vary greatly in their susceptibility to acute toxicity by the dermal route, with the rabbit being the most sensitive species showing moderate toxicity, with the rat and guinea pig showing low toxicity (in descending order). EGBE is a skin and eye irritant; it is not a skin sensitiser. The major target organ effect of EGBE from exposure (regardless of the route of exposure) is the red blood cell (RBC). Animal studies show a hemolytic anemia (haemolysis of RBCs) from acute and chronic exposure to EGBE, resulting in effects in the kidney, liver and spleen. The hemolytic effect of EGBE is caused by the acid metabolite, 2-butoxyacetic acid (BAA). A number of species, including humans and guinea pigs, are relatively insensitive to the hemolytic effects of EGBE. Lifetime rodent studies by the inhalation route showed no carcinogenic effects in rats; however, liver tumours and hemangiosarcomas of the liver were seen in male mice, and forestomach tumours were seen in female mice. These tumours are thought to occur by a non-genotoxic mode-of-action and are only likely to occur in humans, if at all, at unrealistically high exposures (primarily because of kinetic/dynamic differences between mice and humans). Animal studies show that EGBE can cause reproductive and developmental toxicity, but only exposures that also cause parental or maternal toxicity.

B. Toxicokinetics/Metabolism

The toxicokinetics and metabolism of EGBE have been extensively studied and are reviewed in the EU Risk Assessment Report (EU, 2006) and in the U.S. EPA IRIS Toxicological Review of EGBE (U.S. EPA, 2010).

The major metabolite of EGBE is 2-butoxyacetic acid (BAA). EGBE is metabolised to butoxyaldehyde (BAL) by alcohol dehydrogenases, which is then further metabolised to BAA by aldehyde dehydrogenases. The metabolism of EGBE to BAA appears to be a saturable process. The other metabolites of EGBE are (in order of magnitude): the glucuronide conjugate of EGBE (a competing pathway to BAA formation and whose percentage increases relative to dose), the sulfate-conjugate of EGBE and ethylene glycol. Elimination is rapid and occurs mainly by urinary excretion. EGBE does not accumulate in tissues, and the metabolic profile does not change after repeated exposures compared to acute exposures.

Physiologically-based pharmacokinetic (PBPK) models has been developed for EGBE (Corley et al., 1994, 1997, 2005).

C. Acute Toxicity

The oral LD_{50} values for EGBE are presented in Table 2.

Table 2: Acute Oral LD_{50} Values for EGBE

Species	Results (mg/kg)	Klimisch Score	Reference
Rat	1,746 (fasted) 1,746 (fed)	1	ECHA
Rat	880 (male) 614 (female)	2	ECHA
Rat	1,480	2	ECHA
Rat	~1,900	2	ECHA
Rat	2,420	2	ECHA
Rat	2,100 (male) 1,850 (female)	2	ECHA
Mouse	1,519 (fasted) 2,005 (fed)	1	ECHA
Guinea pig	1,414	1	ECHA
Guinea pig	1,200	2	ECHA

The acute inhalation LC_{50} values for EGBE are presented in Table 3.

Table 3: Acute Inhalation LC_{50} Values for EGBE

Species	Exposure	Results (mg/L)	Klimisch Score	Reference
Rat	4-hour LC_0	2.4 (males) 2.2 (females)	1	ECHA
Rat	1- to 3-hour LC_0	> 29	2	ECHA

Species	Exposure	Results (mg/L)	Klimisch Score	Reference
Rat	3-hour LC_0 8-hour LC_{100}	1.44 4.25	2	ECHA
Rat	7-hour LC_{50}	> 4.26	2	ECHA
Rat	4-hour LC_{50} 8-hour LC_{50}	> 3.9 ~3.9	2	ECHA
Rabbit	7-hour LC_{50}	~400 ppm	2	ECHA
Guinea pig	1-hour LC_0	> 3.4 (males) > 3.1 (females)	2	ECHA
Guinea pig	7-hour LC_0	>400 ppm	2	ECHA

The dermal LD_{50} values for EGBE are presented in Table 4.

Table 4: Acute Dermal LD_{50} Values for EGBE

Species	Results (mg/kg)	Klimisch Score	Reference
Rabbit	> 2,000	1	ECHA
Rabbit	> 2,000	1	ECHA
Rabbit	612 (abraded)	2	ECHA
Rabbit	405	2	ECHA
Rabbit	567	2	ECHA
Rat	> 2,000	1	ECHA
Rat	2,275	2	ECHA
Guinea pig	> 2,000	1	ECHA
Guinea pig	0.23 mL/kg (intact) 0.30 mg/kg (abraded)	2	ECHA
Guinea pig	7.3 mL/kg	2	ECHA

D. Irritation

Application of 0.5 mL EGBE to the skin of rabbits for 4 hours under occlusive conditions was irritating. The mean of the 24, 48 and 72-hour erythema scores was 1.7. The mean of the 24, 48 and 72-hour oedema scores were 0.13. The erythema was not fully reversible within 14 days observation period (ECHA) [Kl score = 2]. Another study showed an irritating response to rabbit skin following a 24-hour exposure under occlusive conditions (ECHA) [Kl score = 2].

Instillation of 0.1 mL EGBE into the eyes of rabbits was irritating. The 24, 48 and 72-hour mean scores were: 0.89 for corneal opacity; 0.56 for iridial lesions; 2.6 for conjunctival redness; and 1.8 for chemosis. All effects were reversible within the 21-day observation period (ECHA) [Kl score = 1].

E. Sensitisation

EGBE was not considered to be a skin sensitiser in the guinea pig maximisation test (ECHA) [Kl score = 1].

F. Repeated Dose Toxicity

Oral

Male CR, COBS, CD-BR rats were dosed by oral gavage with 0, 222, 443 or 885 mg/kg EBGE, 5 days/week for 6 weeks. Bloody urine, which persisted through the third week of treatment, was observed in all of the ≥ 443 mg/kg animals; only one 222 mg/kg rat had bloody urine, which disappeared after the week 3 of exposure. Lethargy, unkempt hair coats, piloerection, rates, slight weakness and inactivity were also seen in these animals. Body weights and feed consumption were significantly reduced in the 885 mg/kg animals. Haematological effects were seen in the 885 mg/kg animals and included decreased haemoglobin, total red blood cells (RBCs), and increased MCH in all dose groups and showing a dose-related response. MCHC was decreased and MCV was increased in the ≥ 443 mg/kg animals. Alkaline phosphatase levels were elevated in the ≥ 443 mg/kg animals; and SGPT and glucose levels were increased in the 885 mg/kg group. Absolute and relative spleen and liver weights were increased in the ≥ 443 mg/kg animals. Relative liver weights were also increased in the 222 mg/kg animals. Enlarged, dark spleens were seen in the ≥ 443 mg/kg animals at gross necropsy. Histopathological examination showed stomach hyperkeratosis/acanthosis and splenic congestion in virtually all treated animals at all dose levels. Extramedullary haematopoiesis was observed in the spleens of treated animals. Liver effects were also seen in treated animals and included hepatocytomegally (885 mg/kg only), anisokaryosis (22 and 443 mg/kg), and hemosiderin deposition (≥ 443 mg/kg). Kidney effects were also seen in the treated animals and included hyaline droplet degeneration, proteinaceous casts and hemosiderin in the proximal tubules. The latter two effects were seen in the ≥ 443 mg/kg animals and were considered compound-related; the hyalaine droplets were seen in the controls and its significance is uncertain. The LOAEL for this study was considered 222 mg/kg/day based on adverse effects on the RBC and splenic congestion (it is difficult to discern what were primary effects, and what were secondary to the hemolytic effects); a NOAEL was not established (ECHA) [KI score = 2].

Male and female F344/N rats were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 13 weeks. Based on water consumption, the average daily intake was 0, 69, 129, 281, 367 or 452 mg/kg/day for males and 0, 82, 151, 304, 363 or 470 mg/kg/day for females. Supplemental groups were included for hematology and clinical chemistry observations at weeks 1 and 3. There was no mortality and no clinical signs of toxicity. Reduced body weight gain was seen in the ≥ 4,500 ppm animals, particularly in the females. Water consumption was also reduced in the higher dose groups, particularly for females. At each time point, there was a noticeable macrocytic and mildly hypochromic anemia. Reticulocyte counts were moderately increased in weeks 1 and 13; and erythrocyte counts were decreased at all time points in the ≥ 3,000 ppm males and the ≥ 1,500 ppm males. Thrombocytopenia was consistently observed at all time points in ≥ 4,500 ppm males and females; it also occurred in the 3,000 ppm females at week 13. Alkaline phosphatase was increased in the 6,000 ppm group on week 1 and in the ≥ 4,500 ppm groups on week 13. BUN and creatinine were increased, along with mild decreases in total protein and albumin, occurred at weeks 3 and 13; these changes were considered to be consistent with decreased feed intake. Absolute thymus weight were reduced in the ≥ 4,500 ppm groups. All other organ weight changes were considered secondary to body weight changes. Histopathological effects were seen in the liver, spleen and bone marrow of both male and female rats. The liver changes were primarily centrilobular hepatocellular degeneration and centrilobular Kupffer cell pigmentation. These changes were present in the majority of dosed rats, but they were more prevalent in the ≥ 3,000 ppm animals and were slightly more severe in

females. In addition, the cytoplasm of hepatocytes of treated rats was more eosinophilic and lacked the ampholytic-to-basophilic granularity typical of the controls. In the spleen, there was an increase in haematopoiesis and deposition of hemosiderin. In bone marrow there was an hyperplasia characterised by an increase of hematopoietic cells and decrease in marrow fat cells. All of these lesions were present in the majority of dosed rats, but they were more prominent in the ≥ 3,000 ppm animals. The LOAEL for this study is 750 ppm (69 and 82 mg/kg/day for males and females, respectively) based on the effects seen in the liver. A NOAEL was not obtained (NTP, 1993) [Kl score = 1].

Male and female B6C3F_1 mice were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 14 weeks. Based on water consumption, the average daily intake was estimated to be 0, 118, 223, 553, 676 or 694 mg/kg/day for males and 0, 185, 370, 676, 861 or 1,306 mg/kg/day for females. There was no mortality and no significant clinical signs of toxicity. Reduction in body weight gain was seen in the ≥ 3,000 ppm males and females. Water consumption did not appear to be affected by treatment. Organ weight changes were considered secondary to body weight gain reduction. No treatment-related gross or microscopic lesions in male or female mice were observed. The NOAEL for this study is 223 and 370 mg/kg/day for males and females, respectively. However, this study did not include hematology measurements (NTP, 1993) [Kl score = 1].

Inhalation

Male and female F344 rats were exposed by inhalation to 0, 5, 25 or 77 ppm (0, 24, 121 or 372 mg/m^3) EGBE 6 hours/day, 5 days/week for 90 days. Effects were more pronounced in females than males. In females, there was a slight hemolytic anemia, which was indicated by a minimal depression of RBC counts, haemoglobin and hematocrit; with a slight increase in MCH that was noted at week 2 and at the end of the exposure period. The haematological effects were non-progressive in that there was no increase in severity over time. Reduced body weight gain was seen at week 2, but not at the end of the study. No effects were seen in the males. The NOAECs for males and females were 77 ppm and 25 ppm, respectively (Dodd et al., 1983; ECHA).

Male and female F344/N rats were exposed by inhalation to 0, 31, 62.5, 125, 250 or 500 ppm EGBE 6 hours/day for 14 weeks. Six female rats were found moribund and killed during the study: five in the 500 ppm group and one in the 250 ppm group. Clinical signs were mainly in the ≥ 125 ppm animals and included abnormal breathing, pallor, red urine stains, nasal and eye discharge, lethargy and either increased salivation or lacrimation. All 500 ppm females developed alternating blue and white bands on their tails, particularly during the first two weeks of treatment, that caused them to self-mutilate and loose the distal portion of their tails. The mean final body weights and body weight gains were significantly reduced in the 500 ppm females. There was a persistent and exposure-related macrocytic, normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations, and erythrocyte counts in the ≥ 125 ppm males and ≥ 31 ppm females. The anemia was dose-related and statistically significant; at the lower doses, the effect was small (~5% in the 31 ppm females). Increases in reticulocyte and nucleated erythrocyte counts were seen in the ≥ 125 ppm males and the ≥ 62.5 ppm females, which are indicative of a erythropoietic response. Kidney weight increased in the 500 ppm males and the ≥ 125 ppm females. Liver weights were increased in the ≥ 250 ppm males and the ≥ 125 ppm females. Thymus weights were decreased in the 500 ppm females. There were histopathological changes in the surviving rats. Bone marrow necrosis and infarcts were found in the tails of all surviving 500 ppm females. Minimal hematopoietic cell proliferation of the spleen was seen

in the ≥ 62.5 ppm females and ≥ 250 ppm males. Bone marrow hyperplasia was increased in the ≥ 62.5 ppm females and ≥ 250 ppm males. Increased pigmentation of Kupffer cells in the liver was seen in the ≥ 62.5 ppm females and ≥ 125 ppm males. Renal tubule pigmentation was noted in most of the 250 ppm males, in all of the 500 ppm males, and all of the ≥ 125 ppm females. Minimal forestomach inflammation and hyperplasia were noted in a few of the ≥ 250 ppm males. Epithelial hyperplasia of the forestomach were noted in one female each in the ≥ 250 ppm groups. The NOAEC for males is 62.5 ppm based on haematological changes. The LOAEC for females is 31 ppm based on haematological changes; a NOAEC was not established (NTP, 2000) [Kl score = 1].

Male and female B6C3F_1 mice were exposed by inhalation to 0, 31, 62.5, 125, 250 or 500 ppm 6 hours/day for 14 weeks. There was mortality in the 500 ppm exposure group: two males and two females died; two males and two females were found moribund and were killed. Clinical findings were limited to the 500 ppm males and females that died or were killed. By study termination, body weight gains were significantly reduced in the ≥ 125 ppm males. There was a persistent and exposure-related normocytic (unlike rats), normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations, and erythrocyte counts in the ≥ 125 ppm males and ≥ 31 ppm females. The anemia was dose-related and statistically significant; at the lower doses, the effect on erythrocyte count and haemoglobin was small (1.8% and 2.2% in the 31 and 62.5 ppm females). The normocytic and normochromic erythrocytes were demonstrated by the lack of change in the mean cell volumes and mean cell haemoglobin concentrations, respectively. Relative, but not absolute, liver weighs were increased in the 250 ppm males. At 500 ppm, there were increased relative liver weights (both sexes), absolute liver weights (males), and relative kidney and heart weights (females). The livers of the 500 ppm males and ≥ 250 ppm females showed hemosiderin deposition in the Kupffer cells. Hemosiderin pigmentation was also seen in the kidney tubular cells of the 500 ppm animals (both sexes). Extramedullary hematopoietic cell proliferation (primarily erythroid) was seen in the ≥ 125 ppm males and ≥ 250 ppm females. In the forestomach, increased incidence of inflammation was seen in the ≥ 250 ppm females and epithelial hyperplasia in the ≥ 125 ppm females. The NOAEC for males is 62.5 ppm based on haematological changes. The LOAEC for females is 31 ppm based haematological changes; a NOAEC was not established (NTP, 2000) [Kl score = 1].

Male and female F344/N rats were exposed by inhalation to 0, 31, 62.5 or 125 ppm (0, 151, 302 or 604 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). For haematological and bone marrow analyses, additional groups of animals were exposed to 0, 62.5 or 125 ppm for evaluation at 3, 6 and 12 months; and to 31.2 ppm for 3 months (haematological examination only) and 6 months. Survival was similar across all groups, and there were no treatment-related clinical signs. Body weights of the 125 ppm females were generally lower than the controls from week 17 until study termination. There was a persistent and treatment-related macrocytic, normochromic, responsive anemia, characterised by decreased haematocrit, hemoglobin concentrations and erythrocyte counts at 3, 6 and 12 months in the 62.5 ppm females and the 125 ppm males. Some anemia also occurred at 3 and 6 months in the 31 ppm females and at 12 months in the 62.5 ppm males. In females, the anemia was characterised by a dose-related and significant fall in haematocrit, hemoglobin and erythrocyte count and an increase in MCV. The changes at 31 ppm were small (< 5%). Circulating reticulocyte and nucleated erythrocyte counts are indicative of an erythropoietic response to the anemia. There was about 15-35% decrease in the myeloid/erythroid ratio in the bone marrow of the 125 ppm rats (both sexes), particularly in the females. Significant changes in the ratio were also seen in the 125 ppm males and the 62.5 ppm females, but at only one time point. The severity of the response

was dose-related. Non-neoplastic changes occurred in the nose, liver and spleen. The incidence of hyaline degeneration of the olfactory epithelium were significantly increased in the ≥ 31 ppm males and in the ≥ 62.5 ppm females. The severity was minimal and did not change with increasing exposure concentration. The incidence of Kupffer cell pigmentation of the liver increased significantly in all exposed male and in the ≥ 31 ppm males and in the ≥ 62.5 ppm females; the severity increased in the 135 ppm of both sexes. The incidences of fibrosis in the spleen were significantly increased in the ≥ 62.5 ppm males, but not in females. The LOAEC for males is 31 ppm based on hematology and Kupffer cell pigmentation in the liver. The LOAEC for females is 31 ppm based on Kupffer cell pigmentation in the liver. A NOAEC for either sex was not established (NTP, 2000) [KI score = 2].

Male and female B6C3F_1 mice were exposed by inhalation to 0, 62.5, 125 or 250 ppm (0, 302, 604 or 1,208 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). For haematological and bone marrow analyses, additional groups of animals were exposed to 0, 62.5, 125 or 250 ppm for evaluation at 3, 6 and 12 months. Survival of the ≥ 125 ppm males were significantly less than the controls. Body weights of exposed males were generally less than the controls during the last 25 weeks of the study. The 250 ppm females had body weights that were generally lower (20%) than controls from week 30 to the end of the study. The 62.5 and 125 ppm females had lower body weights from about week 60 until the end of the study. There was a persistent and exposure-related normocytic and normochromic, responsive anemia, characterised by haematocrit, hemoglobin concentrations and erythrocyte counts. In general, the anemia lacked changes in mean cell volumes and mean cell haemoglobin concentrations. There were no treatment-related clinical signs. The changes occurred at the 3-, 6- and 12-month time points in the ≥ 125 ppm males and females. Some anemia also occurred at 6 months in the 62.5 ppm females, and there was some indication of a macrocytosis (as seen by a minimal increase in cell volume) in the 250 ppm females at 12 months. Circulating reticulocyte counts were increased in the ≥ 125 ppm males and females at 3 and 6 months and the 250 ppm females at 12 months; these changes are indicative of an erythropoietic response to the anemia. The bone marrow had no change in either cell counts or myeloid/erythroid ratio. A thromobocytosis (increased platelet counts) developed in the ≥ 62.5 ppm animals at 12 months , in the 250 ppm males at 6 months, the 250 ppm females at 3 and 6 months, and in the 125 ppm females at 6 months. At 62.5 ppm, the females showed reduced haemoglobin, hematocrit, erythrocyte count and increased platelets. The 62.5 ppm males showed an increased platelet count. All these changes were statistically significant with a clear dose-response, but the magnitude was small (< 5%), except for the platelet count (15-20%). Splenic hematopoietic cell proliferation was increased in the ≥ 125 ppm males and 250 ppm females, but it was not accompanied by any change in myeloid/erythroid cell ratio. Increased incidence of hemosiderin pigmentation occurred in the ≥ 62.5 ppm males and ≥ 125 ppm females, and increased bone marrow hyperplasia occurred in the ≥ 125 ppm males. The incidence of hyaline degeneration of the nasal olfactory epithelium and respiratory epithelium was increased in the ≥ 62.5 ppm females (but not in males). The severity of the lesion was minimal and did not change with increasing exposure concentration. There was no clear dose-response. There were forestomach lesions which consisted of ulcers (particularly in females), epithelial hyperplasia that was usually focal, and, particularly in females, frequently associated with ulceration. There was also a number of inflammatory changes in the urogenital system in the male mice only; these changes were not considered to be primarily related to treatment. The LOAEC for this study is 62.5 ppm based on haematological changes and increased platelet counts (at 12 months); a NOAEC was not established (NTP, 2000) [KI score = 1].

Dermal

Male and female New Zealand rabbits were given dermal application of 0, 10, 50 or 150 mg/kg EGBE 6 hours/day for 13 weeks. The highest dose was the maximum that could be tolerated without irritation from prolonged exposure. There were no clinical, haematological effects, clinical chemistry or histopathological changes that were considered treatment-related. The NOAEL for this study is 150 mg/kg/day (ECHA) [KI score = 1].

G. Genotoxicity

In Vitro Studies

Table 5 presents the results of the *in vitro* genotoxicity studies on EGBE.

Table 5: *In Vitro* Genotoxicity Studies on EGBE

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	NTP, 1993; NTP, 2000
Mammalian cell gene mutation (CHO cells/HGPRT)	-	-	1	ECHA
Chromosomal aberration (CHO cells)	-	-	1	NTP, 1993; NTP, 2000

*+, positive; -, negative

In Vivo Studies

Male F344 rats were given a single daily intraperitoneal injection of 0, 7.03. 14.06, 28.12, 56.25, 112.5, 225 or 450 mg/kg EGBE for three consecutive days. Two of the five animals in the 450 mg/kg group died. There was no increase in micronuclei in the bone marrow polychromatic erythrocytes at any dose level (NTP, 2000) [KI score = 1].

Male B6C3F_1 mice were given a single daily intraperitoneal injection of 0, 17.19, 34.38, 68.78, 137.5, 275, 550 or 1,100 mg/kg EGBE for three consecutive days. All the animals in the 1,100 mg/kg group died. There was a statistically significant increase in the number of micronucleated polychromatic erythrocytes in the 137.5 mg/kg dose group only in a pairwise comparison with the controls. The analysis for trend was not significant and it was concluded that the test was negative (NTP, 2000) [KI score = 1].

H. Carcinogenicity

Oral Studies

No studies are available.

Inhalation Studies

Rats: Male and female F344/N rats were exposed by inhalation to 0, 31.2, 62.5 or 125 ppm (0, 151, 302 or 604 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks. Survival was similar across all groups. The incidence of benign or malignant

pheochromocytoma (combined) of the adrenal medulla in females exposed to 125 ppm EGBE was not significantly increased compared to the chamber controls, but it did exceed the historical control range. There was only one malignant pheochromocytoma, which occurred in the 125 ppm group. NTP concluded that there was no evidence for carcinogenicity in male rats and equivocal evidence for carcinogenicity in female rats (NTP, 2000) [KI score = 1].

Mice: Male and female $B6C3F_1$ mice were exposed by inhalation to 0, 62.5, 125 or 250 ppm (0, 302, 604 or 1,208 mg/m^3) EGBE vapour for 6 hours/day, 5 days/week for 104 weeks (NTP, 2000). Survival of the ≥ 125 ppm male mice was significantly less than that of the controls. Increased incidence of tumours was seen in the forestomach of females and liver hemangiosarcomas in males.

Forestomach: There was a positive trend in the incidences of forestomach squamous cell papilloma and squamous cell papilloma or carcinoma combined in female mice. The incidences were significantly increased in the 250 ppm group, in which the only squamous cell carcinoma occurred. These incidences exceeded the historical control range for female mice. There was no significant increase in the incidence of these neoplasms in male mice, but they did exceed the historical control range for male mice. There was one squamous cell carcinoma, but it was in the 125 ppm group.

Liver hemangiosarcomas: There was a positive trend in the incidence of hemangiosarcomas in male mice, which was statistically significant in the 250 ppm group. The incidence at 250 ppm also exceeded the historical control range for this tumour in male mice. There was also a positive trend in the incidence of hepatocellular carcinomas, which was statistically significant in the 250 ppm group. There was, however, no change in the incidence of hepatocellular adenomas and carcinomas combined, because of a reduced incidence of hepatocellular adenomas in the treated groups. The tumour incidence in female mice were not significantly different from the controls.

The NOAEC for tumourigenicity in mice is 125 ppm, based on an increased incidence of liver hemangiosarcomas in males and squamous cell papillomas or carcinomas in females at 250 ppm (NTP, 2000).

I. Mode of Action (MOA) for Mouse Tumours from EGBE Exposure

Liver Hemangiosarcomas

The hypothesised key steps of the MOA are metabolism of EGBE to BAA, hemolysis of RBCs with release of haemoglobin and hepatic hemosiderin accumulation, followed by oxidative stress, modulation of gene expression, cell proliferation, promotion, and neoplasm, leading to the formation of liver tumours (U.S. EPA, 2010). These tumours are unlikely to occur in humans because exposures would have to be much higher than those for rats. *In vitro* data suggest there is a 40- to 150-fold difference in the dose that produces hemolytic changes in the RBCs of humans as compared to rodents. This difference is supported by the Carpenter et al. (1956) study in which no changes in erythrocyte fragility were measured in humans at the highest tested concentration, 195 ppm, but increased erythrocyte fragility was measured in co-exposed rats. In addition, simulations from a PBPK model (Corley et al., 2005) predict that, given the vapour pressure of EGBE, the maximum blood level of BAA that can be obtained from inhalation exposure would be lower than the predicted concentrations from

bolus exposures that have not resulted in hemolytic effects, and lower than concentrations that have been shown to produce an effect on human RBCs *in vitro* (Udden, 2002).

Forestomach Tumours

The incidence of squamous cell papilloma and carcinoma of the forestomach was increased in female mice exposed to 250 ppm EGBE (NTP, 2000). There was also an increase in squamous cell papillomas in male mice, but the incidence was not statistically significant. Forestomach papillomas and carcinomas were not seen in either male or female rats in the 2-year NTP studies. In addition to the tumours, there was also a statistically significant, dose-dependent increase in hyperplasia in mice (both sexes), and for ulceration in female mice. The incidence of ulceration was significantly increased in the 125 ppm male mice.

The hypothesised steps are metabolism to BAA, followed by tissue irritation and subsequent cytotoxicity, compensatory proliferation and the induction of forestomach tumours. Forestomach tumours are unlikely to occur in humans because of the anatomical differences between the human stomach and the mouse forestomach; and because EGBE exposures would have to be higher, if at all possible, in humans than in mice because of the differences between mice and humans in the production and clearance of BAA.

J. Reproductive Toxicity

Male and female Swiss CD-1 mice were given in their drinking water 0 0.5, 1.0 or 2.0% EGBE (equivalent to daily intakes of 0, 720, 1,340 and 2,050 mg/kg/day) during a continuous breeding protocol with a 7-day pre-mating period and a 98-day cohabitation period. There were significant adverse reproductive effects in the females at very high dose levels (≥ 1,340 mg/kg) which also caused severe toxicity, including death. Marginal reductions (3%) in pup weight were noted at 720 mg/kg in the first generation, but not in the second generation. The NOAELs for reproductive and developmental toxicity are 720 mg/kg/day. A NOAEL or LOAEL was not determined for systemic parental toxicity because this protocol is not designed to assess systemic toxicity. However, it was noted that reduced water consumption occurred at all dose levels (Morrissey et al., 1988, 1989; Heindel et al., 1990) [KI score = 1].

Male and female F344/N rats were given in their drinking water 0, 750, 1,500, 3,000, 4,500 or 6,000 ppm EGBE for 13 weeks. Based on water consumption, the average daily intake was 0, 69, 129, 281, 367 or 452 mg/kg/day for males; and 0, 82, 151, 304, 363 or 470 mg/kg/day for females. Testis weights were unaffected by treatment, but the size of the uterus in the ≥ 4,500 ppm groups were reduced. Changes in uterine weight were considered by the authors to be secondary to the reduction in body weight gain rather than a direct effect of EGBE. Sperm concentration was slightly decreased in all treated males (not dose-related); all other sperm measurements were similar to controls. Oestrous cycle length was unaffected by treatment, although the ≥ 4500 ppm females spent more time in diestrous than the other groups. This correlated with the smaller uterine size, which was attributed to a secondary consequence of reduced body weight gain (NTP, 1993; ECHA) [KI score = 1].

K. Developmental Toxicity

Oral Studies

Pregnant female F344 rats were dosed by oral gavage with 0, 30, 100 or 200 mg/kg EGBE on GD 9-11; some animals sacrificed on GD 12 and others sacrificed on GD 20. Another group of pregnant female F344 rats were dosed by oral gavage with 0, 30, 100 or 300 mg/kg EGBE on

GD 11-13; some animals sacrificed on GD 14 and the others sacrificed on GD 20. At ≥ 100 mg/kg on GD 9-11 and GD 11-13, there was marked body weight reduction and/or weight gain, increased kidney and spleen weights, and severe hematotoxicity, in particular marked reduction in circulating red blood cells, haematocrit and hemoglobin, which occurred 24 hours post-treatment. By GD 20, the hematoxic effects were nearly reversed. These changes in organ weights and haematological parameters are indicative of hemolytic anemia and the compensatory haematological changes following cessation of exposure. Increased resorptions, non-live implants and adversely affected implants per litter in the 200 mg/kg treated dams (GD 9 – 11), and decreased foetal platelet count, but no embryolethality, in the 300 mg/kg treated dams (GD 11-13). There were no adverse effects seen on the cardiac system. Increased foetal lethality, but no increase in malformations, occurred in the 200 mg/kg dose (GD 9-11). Increased platelet count was also seen in the foetuses of the 300 mg/kg dose group (GD 11-13). The maternal NOAEL for this study is 30 mg/kg/day. The developmental NOAELs are 100 and 300 mg/kg/day when EGBE was given on GD 9–11 and GD 11-13, respectively (Sleet et al., 1991; ECHA) [Kl score = 1].

In a teratology probe study using the Chernoff-Kavlock assay, pregnant female CD-mice were dosed by oral gavage with 0, 350, 650, 1,000, 1,500 or 2,000 mg/kg EGBE during GD 8 to 14. Maternal toxicity was evident in the dams at dosed of ≥ 650 mg/kg. There were hemolytic effects (≥ 650 mg/kg) and mortality (≥ 1,500 mg/kg). At 1,000 and 1,500 mg/kg, increased resorption rates and numerically reduced number of viable foetuses were observed at 1,000 and 1,500 mg/kg. Cleft palates were seen in 4/43 foetuses (in one litter) at 1,000 mg/kg/day and 1/25 at 1,500 mg/kg. The NOAELs for maternal and developmental toxicity are 350 and 650 mg/kg/day, respectively (Wier et al., 1987; ECHA) [Kl score = 2].

In another Chernoff-Kavlock assay, CD-1 mice were dosed by oral gavage with 1,180 mg/kg/day EGBE (in corn oil) from GD 7 to 14, then allowed to litter and to rear pups to PND 3. Nineteen of the dams died (20%), maternal weight gain was reduced and there were only 24 viable litters (77%) from the surviving dams compared with 97% in the controls. There was no external malformations, pup survival to PND was unaffected and there was no other evidence of developmental toxicity (Schuler et al., 1984; ECHA) [Kl score = 2].

Inhalation Studies

Pregnant female F344 rats were dosed by oral gavage with 0, 25, 50, 100 or 200 mg/kg EGBE on GD 6-15. A dose-related increase in maternal toxicity was observed during the exposure period. There was hematuria (≥ 100 ppm); pale, cold extremities with necrosis of the tail tip (200 ppm); weight loss (≥ 100 ppm), reduction in food consumption (≥ 100 ppm) and water consumption (200 ppm). Absolute and relative organ weight reductions were also noted. Evidence of hemolytic anemia was found in the ≥ 100 ppm dams when blood samples were taken on GD 21. At 200 ppm, there was embryotoxicity (increased resorptions and decreased viable implants per litter) and fetotoxicity (retardations in skeletal ossification). There was no evidence of teratogenicity. The NOAECs for maternal and developmental toxicity are 50 and 100 ppm, respectively (Tyl et al., 1984; ECHA) [Kl score = 2].

Pregnant female New Zealand White rabbits were exposed by inhalation to 0, 25, 50, 100 or 200 ppm EGBE 6 hours/day during GD 6-18. At 200 ppm, four does died or were sacrificed by the third day after the onset of dosing, and four does aborted. All were pregnant. Pregnancy rates were similar across all groups. Body weight loss occurred in all groups including controls during exposure, but the highest difference was in the 200 ppm exposure group; by GD 15, body weights were significantly lower in the 200 ppm group. The high-dose group

had a significant reduction in maternal body weight (8%), gravid uterine weight (22%), and the number of total implants and viable implants. No other developmental effects (including teratogenicity) were noted. The NOAELs for maternal and developmental toxicity are 50 and 100 ppm, respectively (Tyl et al., 1984; ECHA) [Kl score = 2].

Pregnant female SD rats were exposed by inhalation to 0, 150 or 200 ppm EGBE 7 hours/day during GD 7-15. The only maternal effect noted was hematuria in the ≥ 150 ppm dams. There was no developmental toxicity. The NOAEC for developmental toxicity is 200 ppm. A conservative LOAEC for maternal toxicity is 150 ppm, with a NOAEC not established (Nelson et al., 1984) [Kl score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for EGBE follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

An oral RfD was derived by U.S. EPA (2010) based on the findings of the NTP chronic inhalation studies, the rationale being the limited oral database and because the critical endpoint, hemosiderin pigmentation, was more pronounced in the chronic inhalation study (NTP, 2000) versus the available subchronic oral study (NTP, 1993).

U.S. EPA used a route-to-route extrapolation from the NTP (2000) study for the derivation for the RfD. The dose metric used for animal-to-human and route-to-route (inhalation-to-oral) extrapolation for the derivation of the RfD is the area under the curve (AUC) of BAA at 12 months in arterial blood. This dose metric was used for dose-response modelling of chronic inhalation data to derive the point of departure (POD) of 133 µmol-hour/L, expressed as a BMDL based on animal data. The corresponding human BMDL was then back-calculated using the human PBPK model (Corley et al., 1994; Corley et al., 1997) to obtain an equivalent human oral drinking water dose ($BMDL_{HED}$) of 1.4 mg/kg/day. A simplifying assumption was used that the entire dose of drinking water EGBE was consumed over a 12-hour period each day.

Oral Reference Dose (oral RfD)

Oral RfD = $BMDL_{HED}$ / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

- UF_A (interspecies variability) = 1
- UF_H (intraspecies variability) = 10
- UF_L (LOAEL to NOAEL) = 1
- UF_{Sub} (subchronic to chronic) = 1
- UF_D (database uncertainty) = 1
- Oral RfD = 1.4/(1 x 10 x 1 x 1 x 1) = 1.4/10 = 0.14 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (0.14 x 70 x 0.1)/2 = 0.5 mg/L

B. Cancer

Male mice developed hepatocellular carcinomas and hemangiosarcomas that appear to be exposure-related. The incidence of hemangiosarcomas was statistically significant and increased over both concurrent and historical control groups. The hepatocellular carcinomas were within the range of historical controls for male mice but are considered because the dose-response trend is significant and because a similar MOA has been suggested for this tumour. The incidences in the high dose group of these two tumour types were only slightly higher than the upper end of the range for historical controls. These two tumour types were not seen in mice.

The incidence of squamous cell papilloma and carcinoma of the forestomach was increased in female mice exposed to 250 ppm EGBE (NTP, 2000). There was also an increase in squamous cell papillomas in male mice, but the incidence was not statistically significant. Forestomach papillomas and carcinomas were not seen in either male or female rats in the 2-year NTP studies. In addition to the tumours, there was also a statistically significant, dose-dependent increase in hyperplasia in mice (both sexes), and for ulceration in female mice. The incidence of ulceration was significantly increased in the 125 ppm male mice.

The MOAs for these tumours reflect the non-genotoxic nature of EGBE and its metabolites. Both of these MOAs suggests that the MOAs have only limited quantitative significance to humans, principally due to kinetic/dynamic differences from the rodents (U.S. EPA, 2010; ECHA). Because of the MOA, a non-linear approach is used for the dose-response assessment, using the RfD that was derived for the non-cancer assessment. Doses of EGBE below the RfD would not be expected to produce hemolytic effects (i.e., hemosiderin deposition) and therefore is not expected to produce any increase in cancer risk.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

EGBE does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

EGBE is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 6 lists the results of acute aquatic toxicity studies conducted on EGBE.

Table 6: Acute Aquatic Toxicity Studies on EGBE

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Oncorhynchus mykiss	96-hour LC_{50}	1,464	2	ECHA
Pimephales promelas	96-hour LC_{50}	2,137	2	ECHA
Pimephales promelas	96-hour LC_{50}	1,700	2	ECHA
Pimephales promelas	96-hour LC_{50}	1,580	2	ECHA
Lepomis machrochirus	96-hour LC_{50}	1,490	2	ECHA
Daphnia magna	48-hour EC_{50}	1,800	2	ECHA
Daphnia magna	48-hour EC_{50}	1,815	2	ECHA
Daphnia magna	48-hour EC_{50}	881 (cited) 1,100 (recalculated)	2	ECHA
Daphnia magna	48-hour EC_{50}	2,650	2	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50} NOEC	911 (biomass) 88	1	ECHA
Selenastrum capricornutum	72-hour EC_{50} NOEC	720 (biomass) 280	2	ECHA

Chronic Studies

A 21-day fish (*Brachydanio rerio*) study was conducted to examine the potential for endocrine disrupting effects; the study design was based on the OECD TG 204. The NOEC was > 100 mg/L (ECHA) [Kl score = 2].

The NOEC from a 21-day *Daphnia* reproduction study was 100 mg/L (ECHA) [Kl score = 1].

C. Terrestrial Toxicity

No studies are available.

D. Calculation of PNEC

The PNEC calculations for EGBE follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute $E(L)C_{50}$ values are available for fish (1,000 mg/L), *Daphnia* (1,100 mg/L) and algae (911 mg/L). Results from chronic studies are also available for all three trophic levels, with the lowest NOEC being 88 mg/L for algae. On the basis that the data consists of short-term and long-term results from three trophic levels, an assessment factor of 10 has been applied to the lowest reported NOEC of 88 mg/L for algae. The $PNEC_{water}$ is 8.8 mg/L.

PNEC sediment

There are no toxicity data for sediment-dwelling organisms. Therefore, the $PNEC_{sed}$ was calculated using the equilibrium partitioning method. The $PNEC_{sed}$ is 6.5 mg/kg sediment wet weight.

The calculations are as follows:

$PNEC_{sed} = (K_{sed\text{-}water}/BD_{sed}) \times 1000 \times PNEC_{water}$
$= (0.94/1280) \times 1000 \times 8.8$
$= 6.46$ mg/kg

Where:
$K_{sed\text{-}water}$ = suspended matter-water partition coefficient (m^3/m^3)
BD_{sed} = bulk density of sediment (kg/m^3) = 1,280 [default]
$K_{sed\text{-}water} = 0.8 + [0.2 \times Kp_{sed}/1000 \times BD_{solid}]$
$= 0.8 + [0.2 \times 0.30/1000 \times 2400]$
$= 0.94\ m^3/m^3$

Where:
Kp_{sed} = solid-water partition coefficient (L/kg).
BD_{solid} = bulk density of the solid phase (kg/m^3) = 2,400 [default]
$Kp_{sed} = K_{oc} \times f_{oc}$
$= 7.624 \times 0.04$
$= 0.30$ L/kg

Where:
K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for EGBE calculated from EPI Suite™ is 7.624 L/kg.
f_{oc} = fraction of organic carbon in sediment = 0.04 [default].

PNEC soil

There are no toxicity data for terrestrial or soil organisms. Therefore, the $PNEC_{soil}$ was calculated using the equilibrium partitioning method. The $PNEC_{soil}$ is 0.9 mg/kg soil dry weight.

The calculations are as follows:

$PNEC_{soil} = (Kp_{soil}/BD_{soil}) \times 1000 \times PNEC_{water}$
$= (0.15/1500) \times 1000 \times 8.8$
$= 0.88$ mg/kg

Where:

Kp_{soil} = soil-water partition coefficient (m^3/m^3)
BD_{soil} = bulk density of soil (kg/m^3) = 1,500 [default]
$Kp_{soil} = K_{oc} \times f_{oc}$
= 7.624 x 0.02
= 0.15 m^3/m^3

Where:

K_{oc} = organic carbon normalised distribution coefficient (L/kg). The K_{oc} for EGBE calculated from EPI Suite™ is 7.624 L/kg.
f_{oc} = fraction of organic carbon in soil = 0.02 [default].

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Based on information for read-across substance EGBE, EGMHE is readily biodegradable; thus it does not meet the screening criteria for persistence.

Based on a measured log K_{ow} of 0.81 for read-across substance EGBE, EGMHE does not meet the screening criteria for bioaccumulation.

The chronic toxicity data on read-across substance EGBE show NOECs of > 0.1 mg/L. Thus, EGMHE does not meet the screening criteria for toxicity.

The overall conclusion is that EGMHE is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Oral]

Acute Toxicity Category 4 [Dermal]

Acute Toxicity Category 4 [Inhalation]

Skin Irritant Category 2

Eye Irritant Category 1

B. Labelling

Danger

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

Due to structural analogy and clinical data, this material may have a mechanism of intoxication similar to ethylene glycol.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam (alcohol-resistant is preferred), dry chemical or carbon dioxide.

Specific Exposure Hazards

Container may rupture from gas generation in a fire. Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light. Store in the following materials: carbon steel, stainless steel, phenolic lined steel drums. Do not store in: aluminium, copper, galvanised iron, galvanised steel.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace exposure standards have not been established for EGMHE in Australia. The workplace exposure standard for EGBE in Australia is 20 ppm (96.9 mg/m^3) as an 8-hour TWA and a 15-min STEL of 50 ppm (242 mg/m^3) with a skin [absorption] notation.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to this material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

EGMHE is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Carpenter, C.P., Pozzani, U.C., Weil, C.S., Nair, J.H., III, Jeck, G.A., and Smyth, H.F., Jr. (1956). The toxicity of butyl cellusolve solvent. AMA Arch. Ind. Health 14: 114-131.

Corley, R.A., Bormett, G.A., and Ghanayem, B.I. (1994). Physiologically-based pharmacokinetics of 2-butoxyethanol and its major metabolite 2-butoxyacetic acid, in rats and humans. Toxicol. Appl. Pharmacol. 129: 61-79.

Corley, R.A., Markham, D.A., Banks, C., Delorme, P., Masterman, A., and Houle, J.M. (1997). Physiologically based pharmacokinetics and the dermal absorption of 2-butoxyethanol vapor by humans. Fundam. Appl. Toxicol. 39: 120-130.

Corley, R.A., Bartels, M.J., Carney, E.W., Weitz, K.K., Soelberg, J.J., Gies, R.A., and Thrall, K.D. (2005). Development of a physiologically based pharmacokinetic model for ethylene glycol and its metabolite, glycolic acid, in rats and humans. Toxicol. Sci. 85: 476-490.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Dodd, D.E., Snellings, W.M., Maranpot, R.R., and Ballantyne, B. (1983). Ethylene glycol monobutyl ether. Acute, 9 day and 90 day vapor inhalation studies in Fischer 344 rats. Toxicol. Appl. Pharmacol. 68: 405-414.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances.

EU. (2006). European Union Risk Assessment Report on 2-Butoxyethanol (CAS No. 111-76-2), European Chemicals Bureau. Available at: https://echa.europa.eu/documents/10162/e74a38e1-b9e1-4568-92c5-615c4b56f92d.

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Heindel J.J., Gulati D.K., Russel V.S., Reel J.R., Lawton A.D. and Lamb J.C. (1990). Assessment of Ethylene Glycol Monobutyl and monophenol Ether reproductive toxicity using a continuous breeding protocol in Swiss CD-1 mice. Fundam. Appl. Toxicol. 15: 683-696.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Morrissey R.E., Lamb J.C., Schwetz B.A., Teague J.L. and Morris R.W. (1988). Association of sperm, vaginal cytology and reproductive organ weight data with results of continuous breeding reproduction studies in Swiss CD1 Mice. Fundam. Appl. Toxicol. 11: 359-371.

Morrissey R.E., Lamb J.C., Morris R.W., Chapin R.E., Gulati D.K. and Heindel J.J. (1989). Results and evaluations of 48 continuous breeding reproduction studies conducted in mice. Fundam. Appl. Toxicol. 13: 747-777.

National Toxicology Program [NTP]. (1993). Toxicity studies on ethylene glycol ethers administered in drinking water. NIH Publication 93- 3349. NTP Toxicity Report Series No. 26. NTP, Research Triangle Park, NC, USA.

National Toxicology Program [NTP]. (2000). Toxicology and Carcinogenesis Studies of 2-Butoxyethanol (CAS No. 111-76-2) in F344/N rats and B6C3F1 mice (Inhalation studies). NTP Technical Report Series No.484. NIH Publication No. 00-3974.

Nelson, B.K., Setzer, J.V., Brightwell, W.S., Mathinos, PR., Kuczuk, M.H., Weaver, T.E., and Goad, P.T. (1984). Comparative inhalation teratogenicity of four glycol ether solvents and an amino acid derivative in rats. Environ. Health Perspect. 57: 261-271.

Schuler R.L., Hardin B.D., Niemeier R.W., Booth G., Hazelden K., Piccirillo V. and Smith K. (1984). Results of testing 15 glycol ethers in a short term *in vivo* reprotoxicity assay. Environ. Health Perspect. 57: 141-146.

Sleet R.B., Price C.J., Marr M.C., Morrissey R.M. and Schwetz B.A. (1991). Cardiovascular development (CVD) in F-344 rats following phase-specific exposure to butoxy ethanol. Teratol. 43: 466.

Tyl, R.W., Millicovsky, G., Dodd, D.E., Pritts, I., France, K.A., and Fisher, L.C. (1984). Teratogenic evaluation of ethylene glycol monobutyl ether in Fischer 344 rats and new Zealand white rabbits following inhalation exposure. Environ. Health Perspect. 57: 47-68.

Udden, M.M. (2002). Rat erythrocyte morphological changes after gavage dosing with 2-butoxyethanol: a comparison with the in vitro effects of butoxyacetic acid on rat and human erythrocytes. J. Appl. Toxicol. 20: 381-387.

U.S. Environmental Protection Agency [EPA]. (2010). Toxicological Review of Ethylene Glycol Monobutyl Ether (EGBE) (CAS No. 111-76-2) in Support of Summary Information on the Integrated Risk Information System (IRIS). EPA/635/R-08/006F. Available at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0500tr.pdf

U.S. Environmental Protection Agency [EPA]. (2017). EPISuite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface.

Wier P.J., Lewis S.C., and Traul K.A. (1987). A comparison of developmental toxicity evident at term to postnatal growth and survival using ethylene glycol monoethyl ether, ethylene glycol monobutyl ether and ethanol. Teratog. Carcinog. Mutagen. 7: 55-64.

POTASSIUM CHLORIDE

This dossier on potassium chloride presents the most critical studies pertinent to the risk assessment of potassium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained primarily from the OECD-SIDS documents on potassium chloride (OECD, 2001a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Potassium chloride

CAS RN: 7747-40-7

Molecular formula: KCl

Molecular weight: 74.55 g/mol

Synonyms: Potassium chloride

SMILES: [Cl-] [K+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Potassium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid; white crystals	2	ECHA
Melting Point	770°C @ 101.3 kPa	1	ECHA
Boiling Point	1,407°C (pressure not provided)	2	OECD, 2001a,b
Density	1984 kg/m^3	2	ECHA
Vapour Pressure	5.73 hPa @ 906°C	2	OECD, 2001a,b
Partition Coefficient (log Kow)	-	-	-
Water Solubility	255 g/L @ 25°C	2	Lide, 2009; ECHA

III. ENVIRONMENTAL FATE PROPERTIES

Potassium chloride (KCl) dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of potassium (K^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH and organic matter. Potassium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (OECD, 2001b).

Potassium (K^+) and chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001b; Ganong, 1995). Neither potassium chloride nor its dissociated ions are expected to bioaccumulate.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Potassium chloride has low acute toxicity by the oral route. It is not a skin or eye irritant. Long-term studies in rats fed potassium chloride showed no systemic toxicity or carcinogenic effects. Potassium chloride has shown some genotoxic effects in *in vitro* assays; these occurred at high concentrations of potassium chloride and is thought to be due to a disruption of the osmotic balance of the cells. No *in vivo* genotoxicity studies have been conducted on potassium chloride. There were no developmental effects in pregnant female rats and mice given potassium chloride in their diet.

B. Toxicokinetics and Metabolism

Potassium chloride dissociates completely in aqueous solutions to potassium (K^+) and chloride (Cl^-) ions. Potassium is an essential nutrient: it has a number of critical roles, one of which is that it is the principal cation involved in maintaining the osmotic balance of bodily fluids (Ganong, 1995). Both potassium and chloride ions are involved in regulating the acid-base balance of the body (Ganong, 1995).

C. Acute Toxicity

The oral LD_{50} in rats was reported to be 3,020 mg/kg (Boyd and Shanas, 1961) [Kl score = 2].

No acute toxicity studies by the dermal or inhalation route were identified.

D. Irritation

Potassium chloride did not produce an irritant response in an *in vitro* skin irritation (OECD TG 439) test (ECHA) [Kl score = 1].

Potassium chloride did not produce an irritant response in an *in vitro* eye irritation test (ECHA) [Kl score = 2].

E. Sensitisation

No studies were identified.

F. Repeated Dose Toxicity

<u>Oral</u>

Male F344/Slc rats were given 0, 0.25, 1, 5 or 5% potassium chloride in their feed for two years. The mean daily intake was calculated to be 0, 110, 450 or 1,820 mg/kg/day, respectively. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the respective dose groups. Nephritis was predominant in all groups, including the controls. The only treatment-related effect was gastritis (inflammation of the stomach lining). The incidence of gastritis and ulcers were 6%, 18%, 18% and 30% in the 0, 110, 450 and 1,820 mg/kg/day groups, respectively. The gastritis was thought to be indicative of a localised effect due to the irritating nature of the test material. The NOAEL for

systemic effects is 1,820 mg/kg/day, the highest dose tested (Imai et al., 1968; OECD 2001a,b) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. Due to the reduction of feed intake, the mean test substance intake and mean body weight decreased in time. The mean daily intake of potassium chloride was not calculated. There was hypertrophy of the zona glomerulosa in the adrenals (24/50 treated rats versus 4/50 in controls); and cystitis in the urinary bladder (males: 3/59; females 3/50) and single epithelial hyperplasia of the bladder (males 3/50; females 2/50) (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

G. Genotoxicity

In Vitro Studies

Potassium chloride was not mutagenic to *Salmonella typhimurium* strains TA100, TA 1535, TA 1537 and TA 98 strains in an *in vitro* bacterial mutation assay in the absence or presence of metabolic activation (Mortelmans et al., 1986).

Potassium chloride was weakly mutagenic in two separate L5178Y mouse lymphoma assays (Myhr and Caspary,1988; Mitchell et al., 1988). It was mutagenic at 4,000 and 5,000 μg/mL in the presence of metabolic activation in one study, and mutagenic at 7,000 μg/mL in the absence of metabolic activation. The authors stated that these responses are due to high salt concentrations which affect the ionic balance and osmotic pressure of the medium, inducing mutations in cells surviving the treatment.

Potassium chloride induced a significant increase in chromosomal aberrations in Chinese Hamster lung fibroblasts (V79) cells only at the highest test dose (12,000 μg/mL) in the absence of a metabolic activation system. Measurements of the osmotic pressure of the medium showed a two-fold increase at this test compound concentration when compared to the normal medium (530 mOsmol/kg versus 253 mOsmol/kg) (OECD, 2001b).

There are two other reports on the effect of potassium chloride on the formation of chromosome aberrations in Chinese hamster ovary cells (CHO). In these studies potassium chloride concentrations of 75 and 80 mM (approximately 5,500 and 6,000 μg/mL) resulted in 19% and 28% aberrant cells, respectively. An increased number of chromosome aberrations was observed with potassium chloride concentrations that reduced cell survival of 40% or more. The increases in mutagenicity and chromosome aberrations observed in these studies have been considered to be related to cytotoxicity resulting from the high potassium chloride concentrations used (Brusick, 1988).

The reported mutagenic effect of potassium chloride most probably results from a disruption of the osmotic balance of cells with a subsequent interference with chromosomal stability. This may result in the clastogenic effects (DNA breakage and chromosome structural instability) due to K^+ effects on sequestering of Mg^{++} ions required for normal maintenance of chromatin integrity (OECD, 2001b).

In Vivo Studies

No studies have been identified.

H. Carcinogenicity

Oral

F344/Slc male rats were given 0, 110, 450 or 1,820 mg/kg/day potassium chloride in feed for two years. At the end of the study, survival rates were 48%, 64%, 58% and 84% in the 0, 110, 45 and 1,820 mg/kg/day groups. There was no increased incidence of tumours that were considered to be treatment-related (Imai et al., 1968) [Kl score = 2].

Male and female Wistar rats were fed diets containing 0 or 3% potassium chloride over a total period of 30 months. There were no treatment-related differences in tumour response among the groups (Lina and Kuijpers, 2004) [Kl score = 2].

Inhalation

No studies were identified.

Dermal

No studies were identified.

I. Reproductive Toxicity

No studies were identified.

J. Developmental Toxicity

Pregnant Wistar rats were given doses of 3.1 to 310 mg/kg potassium chloride by oral gavage during gestation days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 310 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

Pregnant CD-1 mice were given doses of 2.35 to 235 mg/kg potassium chloride by oral gavage during gestation Days 5 through 15. There was no maternal or developmental toxicity. The NOAEL for maternal and developmental toxicity is 235 mg/kg/day, the highest dose tested (FDRL, 1975) [Kl score = 2].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for potassium chloride follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Two chronic rat feeding studies have been conducted on potassium chloride: only the study by Imai et al. (19686 was conducted with multiple doses and provided mean daily intake values. In this study, the only treatment-related effects were associated with chronic irritation in the gastrointestinal tract (gastritis and ulcers), a localised effect due to the irritating properties of the test material. No systemic toxicity was observed at any of the doses tested. The NOAEL for systemic toxicity in this study is 1,820 mg/kg/day, the highest dose tested. The NOAEL of 1,820 mg/kg/day will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subacute to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 4(10 x 10 x 1 x 1 x 1) = 1,820/100 = 18 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD:

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (18 x 70 x 0.1)/2 = 63 mg/L

Australian Drinking Water Guidelines

The Australian drinking water guideline value for chloride is 250 mg/L based on aesthetics (ADWG, 2011).

B. Cancer

Potassium chloride was not carcinogenic to rats in two chronic feeding studies. Therefore, no cancer reference value was derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Potassium chloride does not exhibit the following physico-chemical properties:

- Flammability
- Explosivity
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Potassium chloride is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

The results of the acute toxicity studies conducted on potassium chloride are presented in Table 2.

Table 2: Acute Aquatic Toxicity Studies on Potassium Chloride

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	880	2	Mount et al., 1997; ECHA
Daphnia magna	48-hour EC_{50}	660	2	Mount et al., 1997; ECHA
Ceriodaphnia dubia	48-hour EC_{50}	630	2	Mount et al., 1997; ECHA
Scenedesmus subspicatus	72-hour EC_{50}	> 100* (growth rate)	1	ECHA

*NOEC = > 100 mg/L

Chronic Studies

In a fish early-life-stage test with the fathead minnow (*Pimephales promelas*), the 7-day NOEC was 500 mg/L (ECHA).

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (820 mg/L), *Daphnia* (660 mg/L) and algae (> 100 mg/L). Although a chronic study was conducted on fish that fulfils the requirements in the OECD TG 210, it is not considered adequate for deriving a PNEC because of the short duration of the test. On the basis of the short-term results from three trophic levels, an assessment factor of 100 has been applied to the lowest reported effect concentration of 100 mg/L for algae. The $PNEC_{water}$ is 1.0 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Potassium chloride dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. Based on its properties, no adsorption of potassium chloride to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of potassium chloride is dominated by its water solubility. Sorption of potassium chloride should probably be regarded as a reversible situation, *i.e.*, the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as potassium chloride. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, potassium chloride is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Potassium chloride is an inorganic salt that dissociates completely to potassium and chloride ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both potassium and chloride ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Potassium and chloride ions are essential to all living organisms, and their intracellular, and extracellular concentrations are actively regulated. Therefore, potassium chloride is not expected to bioaccumulate.

There are no adequate chronic aquatic toxicity studies available on potassium chloride. The acute $E(L)C_{50}$ values for potassium chloride are > 1 mg/L in fish, invertebrates and algae. Therefore, potassium chloride does not meet the screening criteria for toxicity.

The overall conclusion is that potassium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None.

X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact

Wash with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Do not induce vomiting. Rinse mouth with water and then drink a small amount of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Firefighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: potassium oxides, hydrogen chloride, chlorine gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilt

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls/Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for potassium chloride.

Engineering Controls

Use in a well-ventilated area.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Potassium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Boyd, E.M., and Shanas, M.N. (1961). The acute oral toxicity of potassium chloride. Arch. Int. Pharmacodyn. Ther. 133: 275-283.

Brusick, D. (1988). Genotoxic effects in cultured mammalian cells produced by low pH treatment conditions and increased ion concentrations. Environ. Mutag. 8: 879-886.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment (HHRA). (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency (ECHA). (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

FDRL. (1975). Teratological evaluation of FDA 73-78 (KCl) in mice and rats. Final report prepared under DHEW. Contract No. FDA 223-74-2176 by Food and Drug Research Laboratories Inc. Waverly, New York.

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Imai, S., Morimoto, J., Sekiya, N., Shima, M., Kiyozuka, Y., Nakamori, K., Tsubura, Y. (1986). Chronic toxicity test of KCl and NaCl in F344/Scl rats. J. Nara Med. Ass. 37:115-127 [in Japanese]; cited in OECD 2001a,b.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

Lina, B.A.R., and Kuijpers, M.H.M. (2004). Toxicity and carcinogenicity of acidogenic or alkalogenic diets in rats; effects of feeding NH_4Cl, $KHCO_3$ or KCl. Food Chem. Toxicol. 42: 135-153.

Mitchell, A.D., Rudd, C.J., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at SRI international. Env. Molecular Mutagenesis 12(13):37-101.

Mortelmans, K., Haworth, S., Lawlor, T., Speck, W., Tainer, B., Zeiger, E. (1986). Salmonella mutagenicity tests: II. Results from the testing of 270 chemicals. Env. Mutagenesis 8(7):1-119.

Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., and Evans, J.M. (1997). Statistical models to predict the toxicity of major ions to *Ceriodaphnia dubia, Daphnia magna* and *Pimephales promelas* (fathead minnows). Environ. Toxicol. Chem. 16: 2009-2019.

Myhr, B.C., Caspary, W.J. (1988). Evaluation of the L5178Y mouse lymphoma cell mutagenesis assay: Intralaboratory results for sixty-three coded chemicals tested at Litton Bionetics, Inc. Env. Molecular Mutagenesis. 12(13):103-194.

OECD. (2001a). IUCLID Data Set for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

OECD. (2001b). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

SILOXANES AND SILICONES, DIMETHYL, REACTION PRODUCTS WITH SILICA (CAS RN 67762-90-7)
DIMETHYL SILOXANES AND SILICONES (CAS RN 63148-62-9)

This group contains information on dimethyl siloxanes and silicones(CAS RN 63148-62-9) and siloxanes and silicones, dimethyl, reaction products with silica (CAS RN 67762-90-7). They are expected to have similar environmental concerns and have consequently been assessed as a group. Information provided in this dossier is based on dimethyl siloxanes and silicones (CAS RN 63148-62-9).

This dossier presents the most critical studies pertinent to the risk assessment of the siloxanes and their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): dimethyl-bis(trimethylsilyloxy)silane

CAS RN: 63148-62-9

Molecular formula: $C_8H_{24}O_2Si_3$

Molecular weight: 236.53 g/mol

Synonyms: polydimethylsiloxanes (PDMS); octamethyltrisiloxane;, trislocane; octamethyl-;dimeticone,

SMILES: C[Si](C)(C)O[Si](C)(C)O[Si](C)(C)C

Chemical Name (IUPAC): Siloxanes dimethyl reaction products with silica

CAS RN: 67762-90-7

Molecular formula: UVCB substance

Molecular weight: No information is available

Synonyms: hydrophobic silica; PDMS, silicon dioxide reaction product; siliconized silica

SMILES: Not applicable

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of PDMS (CAS RN 63148-62-9)

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	liquid	-	Pubchem
Melting Point	-80.0°C (pressure not provided)	-	Pubchem
Boiling Point	153.0°C (pressure not provided)	-	Pubchem
Density	940 kg/m^3 @ 25°C	-	Pubchem
Vapour Pressure	445.30 Pa (temperature not provided)	-	Pubchem
Partition Coefficient (log K_{ow})	8.21 @ 22°C	-	ECETOC, 20111
Water Solubility	Insoluble	-	EFSA, 2020

No data was available for hydrophobic silica (CAS RN 67762-90-7). As a result, the information provided in this dossier is based on PDMS. PDMS (CAS RN 63148-62-9) and hydrophobic silica (CAS RN 67762-90-7) are linear siloxanes. Siloxanes are the general name for oligomeric or polymeric substances which are characterised by Si-O-Si bonds, methyl groups are usually bound to Si-atoms, but some siloxanes contain vinyl, hydroxyl or other groups in addition (ECETOC, 2011).

NICNAS has assessed PDMS in an IMAP Tier 1 assessment and considers it a polymer of low concern, and concluded that it poses no unreasonable risk to human health and the environment[1] .

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Siloxanes are linear non-volatile substances which are insoluble in water, preferentially strongly adsorb to soil and sediment, and not readily biodegradable. However, they have a low potential for bioaccumulation.

B. Biodegradation

Siloxanes will likely break down slowly via biotic and abiotic processes. Under field conditions, the half-life in soil was 2.4 to 3.9 years. In freshwater sediments, 5 to 10% PDMS was hydrolysed after 1 year (ECETOC, 2011).

If a chemical is found to be not readily or inherently biodegradable, it is categorised as Persistent since its half-life is greater than 60 days (DoEE, 2017).

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=63148-62-9

C. Environmental Distribution

No experimental data are available for siloxanes. However, the soil organic partition coefficient (log K_{oc}) value of 5.162 L/kg (MCI method) was estimated using USEPA EPI Suite™ KOCWIN v2.00 module. Based on this estimated value, the substance is expected to sorb substantially to soils or sediments.

D. Bioaccumulation

There is no evidence of PDMS bioaccumulating in aquatic or terrestrial organisms. Bioconcentration studies suggest that due to their molecular size the potential for PDMS fluids to pass biological membranes, neither the gills nor the gastro-intestinal tract, is very unlikely (ECETOC, 2011).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Siloxanes exhibits low acute toxicity by the oral, inhalation and dermal routes. They are non-irritating to the skin and mildly irritating to the eyes. Siloxanes are not a skin sensitiser. In repeated dose toxicity studies, dose-related changes were observed in rats given ammonium sulfate in feed for 52-weeks. Ammonium sulfate is not genotoxic and is not carcinogenic. No reproductive or developmental effects were observed in read-across studies.

Information provided within this section was obtained from *ECETOC JACC Report No. 55: Linear Polydimethylsiloxanes* as read-across for siloxanes (ECETOC, 2011). [Kl. Score = 2].

B. Acute Toxicity

Oral

The acute oral LD_{50} of PDMS was determined to be > 4,800 mg/kg bw/day in Wistar rats.

Dermal

The acute dermal LD_{50} of PDMS was reported to be > 2,000 mg/kg bw/day. It was also determined that siloxanes do not penetrate the skin.

Inhalation

In an OECD Guideline 403 (inhalation) study, Wistar rats were exposed to PDMS via the nose for four hours. The LC_{50} was determined to be 695 mg/m^3.

C. Irritation

Skin

PDMS mainly causes reversible irritation under extreme conditions like occlusion. Siloxanes are generally considered non-irritating to human skin under normal conditions of use.

Eye

PDMS was found to be mildly irritating to the eye due to conjunctival reactions observed in animal studies.

D. Sensitisation

PDMS is not expected to be sensitising to human skin based on the results from a clinical HRIPT.

E. Repeated Dose Toxicity

Oral

In a combined chronic toxicity and oncogenicity study, PDMS was administered to 30 Fischer 344 rats via their diet at dose levels of 0, 100, 300 or 1,000 mg/kg bw/day for 24 months. Ten animals were necropsied following 12 months of treatment. 20 animals were treated for 12 months followed by a 12-month recovery period. Possible substance-related findings were limited to increased incidences of eye opacity in the chronic recovery group. The NOEL for systemic toxicity was determined to be 1,000 mg/kg bw/day, the highest tested dose.

Inhalation

No data were available .

Dermal

In a 4-week study, siloxanes were dermally administered to New Zealand White rabbits. After 6 hours of exposure, the animals were observed daily for 29-30 days. Dermal application of siloxanes was considered non-toxic and the NOAEL for this study was reported to be 1,000 mg/kg bw/day.

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on PDMS based are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Siloxanes

Test System[1]	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) S. typhimurium	-	-	2	ECETOC, 2011
OECD Guideline 471 (Bacterial Reverse Mutation Assay) Salmonella typhimurium (TA98, TA100, TA135, TA1537, and TA1538)	-	-	2	ECETOC, 2011

*+, positive; -, negative.

In Vivo Studies

No data were available.

G. Carcinogenicity

Oral

In a combined chronic toxicity and oncogenicity study, PDMS was administered to 60 Fischer 344 rats via their diet at dose levels of 0, 100, 300 or 1,000 mg/kg bw/day for 24 months. No substance-related neoplastic or pre-neoplastic changes were observed. The NOEL for oncogenicity was 1,000 mg/kg bw/day, the highest tested dose. There was no indication of carcinogenicity of PDMS.

Inhalation

No data were available.

Dermal

No data were available.

H. Reproductive Toxicity

Oral

Male Sprague-Dawley rats were exposed to PDMS via their drinking water for four weeks. No clinical signs of toxicity were noted. The NOAEL for this study was reported to be > 1,000 mg/kg bw/day.

Dermal

Albino rabbits were exposed to PDMS via dermal application for four weeks. There were no reproductive effects observed following dermal application of siloxanes. The NOAEL was reported to be > 3,000 mg/kg bw/day.

Charles River CD rats were implanted with a cross-linked silicone gel for up to 61 days. There was no treatment-related mortality reported. No differences in behaviour and general condition, body weight gain or reproductive behaviour and success were recorded in the parental generation. The NOAEL was reported to be 28,500 mg/kg bw/day in dams and offspring.

I. Developmental Toxicity

The teratogenicity of PDMS was evaluated using in pregnant New Zealand White rabbits. Dose levels ere 3, 10, or 30 ml/kg bw/day. Rabbits were implanted 6 weeks prior to insemination. On Day 29 of gestation all surviving animals were necropsied. There were no significant differences between treated and untreated mice. There were also no adverse effects observed in this study. The maternal and developmental NOAEL was 30 ml/kg bw/day (28,500 mg/kg bw/day).

In another study, three groups of 23 pregnant New Zealand White rabbits were administered siloxanes via oral gavage. There were no reproductive changes observed. The NOAEL was determined to be 1,000 mg/kg bw/day.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for siloxanes follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

The NOAEL from a rat 2-year oral feeding study on PDMS was reported to be 1,000 mg/kg bw/day. This NOAEL will be used for determining the oral reference dose (RfD) and the drinking water guidance value for siloxanes.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 1
UF_D (database uncertainty) = 1
Oral RfD = 1000/(10 x 10 x 1 x 1 x 1 x 1) = 1000/100 = 10 mg/kg/day

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (10 x 70 x 0.1)/2 = 70/2 = 35 mg/L

B. Cancer

Siloxanes are not considered carcinogens. Thus, a cancer reference value will not be calculated for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Siloxanes does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Siloxanes are of low toxicity concern to aquatic, sediment-dwelling and terrestrial organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity data for PDMS.

Table 3: Acute Aquatic Toxicity Studies on PDMS

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Chanel Catfish (*Ictalurus punctatus*)	72-hour LC_{50}	5.5	2	ECOTOX
Daphnia magna	48-hour LC_{50}	44.5	2	ECOTOX

Chronic Studies

A 7-day fish (*Ictalurus punctatus*) freshwater study was identified in ECOTOX. The reported LC_{50} was 3.16 mg/L [Kl. Score = 2].

C. Sediment Toxicity

Table 4 lists the results of chronic toxicity data for PDMS in sediment-dwelling organisms.

Table 4: Chronic Sediment Toxicity Studies on PDMS

Test Species	Endpoint	Results (mg/kg dw)	Klimisch score	Reference
Chironomus tentans (midge larva)	20-day NOEC	>2,590	2	ECETOC, 2011
Chironomus tentans	14-day NOEC	>560[a]	2	ECETOC, 2011
Hyallela azteca (freshwater amphipod)	28-day NOEC	<2,200	2	ECETOC, 2011
Hyallela azteca	42-day NOEC	>994	2	ECETOC, 2011
Nereis diversicolor (marine polychaeta, ragworm)	28-day NOEC	>1,000	2	ECETOC, 2011

a – maximum concentration tested in the study. No effects observed at any tested concentration.

D. Terrestrial Toxicity

Table 5 lists the results of chronic toxicity data for PDMS in soil-dwelling organisms.

Table 5: Chronic Terrestrial Toxicity Studies on PDMS

Test Species	Endpoint	Results (mg/kg dw)	Klimisch score	Reference
Eisenia foetida (earthworms)	21-day NOEC	>1,100	2	ECETOC, 2011
Folsomia candida (springtail)	28-day NOEC[a]	230	2	ECETOC, 2011
Soil microflora	28-day NOEC	>1,000	2	ECETOC, 2011

a – soil microflora activity evaluated on day 0, 14 and 28 and on day 58 for mineralization only

E. Calculation of PNEC

The PNEC calculations for siloxanes follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute E(L)C_{50} values are available for fish (5.5 mg/L) and *Daphnia* (45.5 mg/L). Results from chronic studies are also available for fish (3.16 mg/L). On the basis that the data consists of short-term and long-term results from two trophic levels, an assessment factor of 50 has been applied to the lowest reported LC_{50} value of 3.16 mg/L for fish. Therefore, the $PNEC_{water}$ is 0.0632 mg/L.

PNEC sediment

Siloxanes are expected to partition more readily to the sediment phase rather than the aquatic phase. No adverse effects were observed in any of the chronic studies on sediment-dwelling organisms. Results are available for three trophic levels and the lowest NOEC is 560 mg/kg dw. An assessment factor of 50 has been applied to this value. Therefore, the $PNEC_{sediment}$ is 11.2 mg/kg .

PNEC soil

Results are available for three tropic levels (soil mico-organisms, earthworms and arthropods) and the lowest NOEC is 230 mg/kg dw for *Folsomia*. An assessment factor of 10 has been applied to the lowest NOEC value. Therefore, the $PNEC_{soil}$ is 23 mg/kg.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Siloxanes are not readily biodegradable. Thus, they meet the screening criteria for persistence.

There is no evidence of PDMS bioaccumulating in aquatic or terrestrial organisms. Bioconcentration studies suggest that due to their molecular size the potential for PDMS

fluids to pass biological membranes, neither the gills nor the gastro-intestinal tract, is very unlikely (ECETOC, 2011). Thus, siloxanes do not meet the screening criteria for bioaccumulation.

The chronic toxicity data on PDMS show NOECs of > 0.1 mg/L. Acute LC50 values are > 1.0 mg/L. Thus, siloxanes do not meet the screening criteria for toxicity.

The overall conclusion is that siloxanes are not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

H226: Flammable liquid and vapour

H319: Causes serious eye irritation

H410: Very toxic to aquatic life with long-lasting effects

B. Signal word

Warning

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Please refer to the product SDS for additional information and for confirmation of the information provided herein.

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of the body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for siloxanes.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure self-contained breathing apparatus. The following should be an effective type of air-purifying respirator: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: none

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

European Centre for Ecotoxicology and Toxicology of Chemicals [ECETOC]. (2011). ECETOC JACC Report No. 55: Linear Polydimethylsiloxanes CAS No. 63148-62-9 (Second Edition). December 2011.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

ECOTOX. USEPA ECOTOXicology Knowledgebase (ECOTOX). https://cfpub.epa.gov/ecotox/index.cfm

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

Stevens. (1998). Environmental fate and effects of dimethicone and cyclotetrasiloxane from personal care applications. International Journal of Cosmetic Science – Wiley Online Library.

U.S. Environmental Protection Agency [EPA]. (2017). EPI Suite™ v. 4.11, United States Environmental Protection Agency, Office of Pollution Prevention and Toxics and Syracuse Research Corporation. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

SODIUM CHLORIDE

This dossier on sodium chloride presents the most critical studies pertinent to the risk assessment of sodium chloride in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): sodium; chloride

CAS RN: 7647-14-5

Molecular formula: NaCl

Molecular weight: 58.44 g/mol

Synonyms: Halite, Salt, Table salt, Saline, Rock salt, Common salt, Dendritis, Purex'

SMILES: [Cl-].[Cl-].[Ca+2]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Chloride

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystaline solid	-	ECHA
Melting Point	801 °C @ 101.3 kPa	-	ECHA
Boiling Point	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Density	2163 kg/m^3 @ 20 °C	1	ECHA
Vapour Pressure	The study does not need to be conducted, because NaCl is a solid which melts above 300°C.	1	ECHA
Partition Coefficient (log K_{ow})	The study does not need to be conducted, because NaCl is inorganic.	1	ECHA
Water Solubility	317 g/L @ 20°C	2	ECHA
Dissociation Constant (pKa)	Not applicable, NaCl is an electrovalent substance.	-	ECHA

III. ENVIRONMENTAL FATE SUMMARY

Sodium chloride (NaCl) dissociates completely in aqueous solutions to sodium (Na^+) and chloride (Cl^-) ions. Sodium chloride and its dissociated ions are ubiquitous in the environment.

The transport and/or leaching of sodium (Na^+) and chloride (Cl^-) ions is affected by clay minerals (type and content), pH, and organic matter. Similar to potassium, sodium ions are less mobile and less prone to leaching than anions in soil, such as chloride and nitrate (NO_3^-). Chloride binds only weakly to soil particles, and therefore follows water movement (DoEE, 2017; OECD, 2001).

Chloride (Cl^-) ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated (OECD, 2001). Neither sodium chloride nor its dissociated ions are expected to bioaccumulate.

Release to surface waters under the assessed circumstances is expected to have limited long-term environmental effects as these salts are ubiquitous and are present in most water, soil and sediment, therefore organisms are adapted to a level of exposure. The magnitude of the acute effect for a receiving aquatic environment would depend on the released concentrations as well as the degree of adaptation of species present to these naturally occurring ions and salts (DoEE, 2017).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Historically, sodium chloride (as a major ingredient in edible salt) has been commonly used in cooking as a condiment and food preservative. Sodium is an electrolyte that regulates the amount of water in your body and also plays a part in nerve impulses and muscle contractions. When depleted in the body, sodium must be replaced in order to maintain intracellular osmolarity, nerve condition, muscle contraction and normal renal function. Sodium chloride is used to treat or prevent sodium loss caused by dehydration, excessive sweating or other causes.

The NHMRC has established dietary guidelines for the intake of sodium per day (adult) as less than 2,000 mg sodium per day (NHMRC, 2007 updated 2017). Sodium chloride is categorised under GRAS (Generally Recognised as Safe) by the FDA (U.S. Food and Drug Administration) and the average daily levels of sodium intake for adults range from 2 to 5 grams. A technical report by WHO and the Food and Agriculture Organization (FAO) recommended the consumption of less than 5 grams sodium chloride (or 2 grams sodium) per day as a population nutrient intake goal, while ensuring that the salt is iodised (WHO, 2007).

NICNAS has assessed sodium chloride in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health or the environment[1] .

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber= 7647-14-5

Sodium chloride has low acute toxicity by the oral, dermal or inhalation route. It is not a skin irritant or a skin sensitiser. Long-term studies in rats fed sodium chloride showed elevated blood pressure. It is not a carcinogen and nor a developmental toxicant.

B. Acute Toxicity

Oral

The acute oral LD_{50} values of sodium chloride in rats is greater than 3,550 mg/kg with fiducial limits of 3,040 – 4,140 mg/kg (ECHA) [KI scores = 2].

Dermal

A dermal toxicity study was conducted in rabbits and the LD_{50} value was greater than 10,000 mg/kg and hence not classified according to EU Annex VI (ECHA) [KI scores = 2].

Inhalation

An acute inhalation toxicity study was conducted at a dose of 42 mg/L administered as an aerosol of a 20% aqueous solution to male rats and the results of the study indicated that the LC_{50} of sodium chloride was greater than 42 mg/L (42,000 mg/m^3) and hence not classified (ECHA) [KI scores = 2].

C. Irritation

Skin

When in contact with the intact skin, sodium chloride causes no response, either in undiluted form or in solution. Sodium chloride is considered to be slightly to not irritating to the skin (ECHA) [KI score = 2].

Eye

No adequate or reliable studies are available.

D. Sensitisation

Sodium chloride is not considered to be a skin sensitiser (ECHA).

E. Repeated Dose Toxicity

Oral

The estimated fatal dose of sodium chloride is approximately 0.75 to 3.00 g/kg (HSDB - Hazard Substance Data Bank - 750 to 3000 mg/kg). The lowest toxic dose (TDLo) for an adult man with normal blood pressure is 8,200 mg/kg (Patty's Handbook of Toxicology). High oral sodium chloride intake is associated with increased risk of hypertension; however, this is a well studied field in humans and additional animal testing data would not add value. Based on the studies, sodium chloride is not classified for any repeated dose effects.

A two-year feeding study was conducted to investigate the impact of sodium chloride on rats. Animals received a chronic administration at doses of 4% sodium chloride over a period

of 2 years which induces elevated blood pressure in the rats. The LOAEL from this key study identified a dose level of < 4% via the diet and the calculated LOAEL was 2,533 mg/kg/day (ECHA).

Dermal

No adequate or reliable studies are available.

Inhalation

No adequate or reliable studies are available.

F. Genotoxicity

No adequate or reliable studies are available.

G. Carcinogenicity

Sodium chloride is not classified as a carcinogen (ECHA). Sodium chloride is not listed with IARC.

H. Reproductive Toxicity

No adequate or reliable studies are available.

I. Developmental Toxicity

Sodium chloride is not classified as a developmental toxicant (ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The Australian drinking water guideline value for chloride ions is 250 mg/L based on aesthetics (ADWG, 2011).

The Australian drinking water guideline value for sodium ions is 180 mg/L based on aesthetics (ADWG, 2011).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium chloride does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Sodium chloride is of low acute toxicity concern to aquatic organisms, in part because of the effect of pH changes from the dissociated hydrogen ion.

B. Aquatic Toxicity

Acute Studies

The 96-hour LC_{50} value of 5,840 mg/L for sodium chloride was determined in a continuous flow-through exposure system with bluegill sunfish (*Lepomis macrochirus*) (ECHA) [KI score =1].

The EC_{50} 48-hour (immobilisation, *Daphnia magna*) was determined to be 1,900 mg/L (ECHA) [KI score = 2].

The EC_{50} of NaCl at 96 hours to *Lemna* was determined for comparison and found to be 6,870 mg/L (6.87 g/L) (ECHA) [KI score = 1].

Chronic Studies

The 33-day NOEC value of 252 mg/L for sodium chloride was determined in a continuous flow-through exposure system with early life stage fathead minnows (*Pimephales promelas*) (ECHA) [KI score = 2].

A 21-day NOEC (reproduction, *Daphnia pulex*) was determined to be 314 mg/L (ECHA) [KI score = 2].

C. Terrestrial Toxicity

The mean 14-day LC_{50} for three experiments conducted with the earthworm, *E. fetida* was 3,296 mg NaCl/kg soil dw. The 10-week NOEC (based on mortality) was 3,507 mg NaCl/kg soil for the earthworm, *E. fetida* (ECHA) [KI score = 2].

In a 7-day exposure study with red fescue grass, the EC_{50} for germination was 500.8 mg NaCl/kg soil dw. In a 7-day exposure study with Kentucky bluegrass, the NOEC for stem growth was 243 mg NaCl/kg soil dw (ECHA) [KI score = 2].

The 12-hour LD_{50} for wild house sparrows was approximately 3,000 - 3,500 mg/kg NaCl (ECHA) [KI score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium chloride is an inorganic mineral. Thus, biodegradation is not applicable to this substance. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium chloride.

Bioaccumulation in fish is not expected given the inorganic nature of the substance. Thus, sodium chloride does not meet the screening criteria for bioaccumulation.

The NOECs from the chronic aquatic toxicity studies on sodium chloride are greater than 0.1 mg/L. The E(L)C_{50} values from the acute aquatic toxicity studies on sodium chloride are > 1 mg/L. Thus, sodium chloride, does not meet the criteria for toxicity.

The overall conclusion is that sodium chloride is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not Classified

B. Labelling

No signal word.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.

Skin Contact

Wash thoroughly with soap and water.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Keep product and empty container away from heat and sources of ignition. May emit toxic fumes of chloride and sodium oxide (above 1,413°C). Depending on conditions, decomposition products may include hydrogen chloride gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Prevent from entering sewers, waterways, or low areas.

Steps to be Taken if Material is Released or Spilled

Soak up with inert absorbent material.

D. Storage And Handling

General Handling

Keep product and empty container away from heat and sources of ignition. Ensure adequate ventilation, especially in confined areas.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for choline chloride.

Engineering Controls

Good general ventilation should be used.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is recommended. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

Sodium chloride is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment and Energy [DoEE]. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report prepared by the Chemicals and Biotechnology Assessments Section (CBAS), in the Chemicals and Waste Branch of the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

HSBD. Hazardous Substances Data Bank. https://pubchem.ncbi.nlm.nih.gov/source/hsdb/6368

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NHMRC. (2007). Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes, Version 1.2 updated September 2017. National Health and Medical Research Council. Department of Health and Ageing. Australian Government.

OECD. (2001). Screening Information Assessment Report (SIAR) for Potassium chloride (CAS No. 7447-40-7), UNEP Publications. Available at: https://hpvchemicals.oecd.org/UI/SIDS_Details.aspx?id=68BF142A-D550-432C-8C48-13883944BA1D.

Patty's Toxicology, 6 Volume Set, 6th Edition. Volume 3: 375. July 2012.

WHO. (2007) Reducing salt intake in populations: report of a WHO forum and technical meeting. https://www.who.int/dietphysicalactivity/Salt_Report_VC_april07.pdf. Accessed 28 Apr 2020

SODIUM HYDROXIDE

This dossier on sodium hydroxide presents the most critical studies pertinent to the risk assessment of sodium hydroxide in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The information presented in this dossier was obtained from the OECD-SIDS documents on sodium hydroxide (OECD, 2002a,b) and the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium hydroxide

CAS RN: 1310-73-2

Molecular formula: HNaO

Molecular weight: 40 g/mol

Synonyms: Caustic soda, soda lye, NaOH

SMILES: O[Na]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-Chemical Properties of Sodium Hydroxide

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	Lide, 2009; ECHA
Melting Point	318°C (solid, 100%); 52°C (60% solution)	2	ECHA
Boiling Point	1,388°C @ 101.3 kPa	2	Lide, 2009; ECHA
Density	2130 kg/m^3, 20°C (100%) 1430 kg/m^3, 20°C (40%)	2	Lide, 2009; ECHA
Vapour Pressure	1 Pa @ 513°C	2	Lide, 2009; ECHA
Partition Coefficient (log K_{ow})	Not applicable	-	-
Water Solubility	Very soluble (>10 g/L @ 25°C)	2	Lide, 2009; ECHA
Dissociation Constant (pKa)	14.8 @ 25°C	2	Lide, 2009; ECHA
pH of 5% NaOH solution	14	2	O'Neil, 2006

Sodium hydroxide (NaOH) is a strong alkaline substance that dissociates completely in water to sodium (Na^+) and hydroxyl (OH^-) ions.

III. ENVIRONMENTAL FATE PROPERTIES

Due to its high water solubility and low vapour pressure, sodium hydroxide will be found predominantly in the aquatic environment where it dissociates completely to sodium (Na^+) and hydroxyl (OH^-) ions. Both ions are ubiquitous in the environment (UNEP, 1995).

The addition of sodium hydroxide to an aquatic ecosystem may increase the pH depending on the buffer capacity of the receiving water. In general, the buffer capacity is regulated by the equilibria between CO_2, HCO_3^- and CO_3^{2-}:

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ ($pKa_1 = 6.35$)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ ($pKa_2 = 10.33$)

A release of sodium hydroxide into the aquatic environment from the use of NaOH could potentially increase the sodium concentration and the pH in the aquatic environment. Table 2 shows the concentration of sodium hydroxide needed to increase the pH to values of 9.0, 10.0, 11.0 and 12.0.

Table 2: Sodium Hydroxide Concentration (mg/L) Needed to Increase pH (DeGroot et al., 2002; taken from OECD, 2002b)

Buffer capacity*	Final pH			
	9.0	10.0	11.0	12.0
0 mg/L HCO_3 (distilled water)	0.4	4.0	40	400
20 mg/L HCO_3 (10th percentile of 77 rivers)	1.0	8.2	51	413
106 mg/L HCO_3^- (mean value of 77 rivers)	3.5	26	97	468
195 mg/L HCO_3^- (90th percentile of 77 rivers)	6.1	45	145	525

*The initial pH of a bicarbonate solution with a concentration of 20-195 mg/L was 8.25 to 8.35.

Na^+ and OH^- ions will not adsorb on the particulate matter or surfaces and will not accumulate in living tissues (OECD, 2002b).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Limited toxicity data exist for sodium hydroxide (NaOH). Depending on the concentration, solutions of NaOH are corrosive, irritating or non-irritating. These solutions cause direct effects to the skin, eyes, respiratory tract and gastrointestinal tract. Vapours from aqueous solutions of KOH can cause respiratory irritation. NaOH is not a skin sensitiser. There are no repeated dose, reproductive and developmental toxicity studies on sodium hydroxide.

B. Toxicokinetics/Metabolism

Sodium hydroxide dissociates completely in aqueous solutions to sodium (Na^+) and hydroxyl (OH^-) ions. Sodium is an essential nutrient involved in fluid and electrolyte balance and is required for normal cellular function (Ganong, 1995). Sodium is the major extracellular cation in the body; the total body content is tightly regulated (Ganong, 1995).

C. Acute Toxicity

There are no oral toxicity guideline studies on sodium hydroxide. An oral LD_{50} of a 1 to 10% solution of NaOH in rabbits was reported to be 325 mg/kg (expressed as 100% NaOH) (OECD, 2002a,b). Mortality was also observed when a 1% NaOH solution was dosed, but in this case, the applied volume was relatively high (24 mL per kg body weight) (OECD, 2002a,b).

Acute toxicity studies were not identified for the inhalation and dermal route.

D. Irritation

Animal studies have shown that an 8% NaOH solution is corrosive to the skin. In humans, 0.5 to 4% NaOH concentrations produced skin irritation; and, based on the results of two different human patch tests, a NaOH solution that is slightly less than 0.5% would be non-irritating to human skin (OECD, 2002a,b).

Results from animal eye irritation studies indicate that a 0.2-1.0% NaOH solution would be non-irritating, while 1.2 or > 2% NaOH solutions would be corrosive (OECD, 2002a,b).

E. Sensitisation

Male volunteers were exposed on the skin of their back to solutions of 0.063 to 1.0% NaOH in the induction phase of a human patch test. After 7 days the volunteers were challenged to a concentration of 0.125% NaOH. The irritant response correlated well with the concentration of NaOH, but an increased response was not observed when the previously patch tested sites were re-challenged. Based on this study, sodium hydroxide is not a skin sensitiser (OECD, 2002a,b; ECHA) [Kl. score = 2].

F. Repeated Dose Toxicity

No studies were identified for the oral and dermal route. An inhalation study was conducted in rats exposed to aerosols of solutions of NaOH ranging from 5% to 40%. Exposures were twice weekly (hours/day and total exposure days unspecified). All animals in the 40% solution group died within a month mostly from bronchopneumonia. At the lower concentrations, respiratory tract lesions were observed; an NOAEL was not identified (NIOSH, 1975).

G. Genotoxicity

In Vitro Studies

Several *in vitro* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

In Vivo Studies

Several *in vivo* studies have been conducted on NaOH (OECD, 2002a,b; ECHA). Although these studies reported negative results, they are considered unreliable (Kl. score = 3) due to methodological or reporting deficiencies.

H. Carcinogenicity

No studies were identified.

I. Reproductive Toxicity

No valid studies were identified regarding toxicity to reproduction in animals after oral, dermal or inhalation exposure to NaOH.

J. Developmental Toxicity

No valid studies were identified regarding developmental toxicity in animals after oral, dermal or inhalation exposure to NaOH (OECD, 2002a,b; ECHA).

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Oral and dermal repeated dose, reproductive, and developmental toxicity studies have not been conducted on NaOH. A repeated dose toxicity study was conducted by the inhalation route, but the methodology and documentation preclude its use for deriving a toxicological reference value. These toxicity studies would have questionable usefulness because of the corrosive/irritating nature of NaOH, which would limit the amount absorbed. NaOH dissociates to sodium and hydroxyl ions in bodily fluids, and a significant amount of these ions are already ingested in foods. Furthermore, both ions are present in the body and are highly regulated by homeostatic mechanisms. Thus, a toxicological reference value was not derived for NaOH.

The Australian drinking water guideline values for sodium (180 ppm, aesthetic) and pH may be applicable (ADWG, 2021).

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium hydroxide does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Sodium hydroxide has low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

The OECD-SIDS SIAR on NaOH states that while the toxicity of the NaOH has been assumed to be related to the hydroxyl anion, in general a pH change could influence the speciation of other chemicals and therefore increase and/or decrease toxicity of the substance.

There are no guideline studies on NaOH; the studies summarised below have Klimisch scores of 3 or 4.

Acute Fish

The 24-hour LC_{50} to *Carassius auratus* (goldfish) is 160 mg/L. At 100 mg/L, which was equivalent to a pH of 9.8, no mortality was observed. The 48-hour LC_{50} to *Leuciscus idus melanotus* is 189 mg/L. The 96-hour LC_{50} of *Gambusia affinis* (mosquitofish) is 125 mg/L. At 84 mg/L, no effects on the fish were observed. The pH was 9 at 100 mg/L.

Acute Invertebrate

The 48-hour LC_{50} is 40 mg/L for *Ceriodaphnia cf. dubia*. The toxicity threshold concentration of NaOH for *Daphnia magna* was reported to range from 40 to 240 mg/L.

Acute Algae

No studies were identified.

C. Terrestrial Toxicity

No studies were identified.

D. Calculation of PNEC

The OECD-SIDS SIAR on NaOH states the following regarding the aquatic toxicity studies on NaOH (OECD, 2002b):

> *"In many cases pH, buffer capacity and/or medium composition were not discussed in the publications, although this is essential information for toxicity tests with NaOH. This is the most important reason why most of the studies, mentioned above were considered invalid. Although valid acute ecotoxicity tests and chronic ecotoxicity tests with NaOH are not available, there is no need for additional testing with NaOH. A significant number of acute toxicity tests are available, and the results of the tests are more or less consistent. Altogether they give a sufficient indication of acute toxicity levels of sodium hydroxide."*
>
> *"Furthermore, acute toxicity data cannot be used to derive a PNEC or a PNEC added for sodium hydroxide. Aquatic ecosystems are characterised by an alkalinity/pH, and the organisms of the ecosystem are adapted to these specific natural conditions. Based on the natural alkalinity of waters, organisms will have different optimum pH conditions, ranging from poorly buffered waters with a pH of 6 or less to very hard waters with pH values up to 9. A lot of information is available about the relationship between pH and ecosystem structure and also natural variations in pH of aquatic ecosystems have been quantified and reported extensively in ecological publications and handbooks."*
>
> *"Normally a PNEC or a PNEC added has to be derived from the available ecotoxicity data. A PNEC added is a PNEC which is based on added concentrations of a chemical (added risk approach). Based on the available data it is not considered useful to derive a PNEC or a PNEC added for NaOH because:*
>
> - *The natural pH of aquatic ecosystems can vary significantly between aquatic ecosystems,*

- *Also, the sensitivity of the aquatic ecosystems to a change of the pH can vary significantly between aquatic ecosystems and*
- *The change in pH due to an anthropogenic NaOH addition is influenced significantly by the buffer capacity of the receiving water."*

"Although a PNEC or a PNEC added was not calculated for NaOH, there is a need to assess the environmental effect of a NaOH (alkaline) discharge. Based on the pH and buffer capacity of effluent and receiving water and the dilution factor of the effluent, the pH of the receiving water after the discharge can be calculated. Of course, the pH change can also be measured very easily via a laboratory experiment or by conducting field measurements. The change in pH should be compared with the natural variation in pH of the receiving water and based on this comparison it should be assessed if the pH change is acceptable."

Based on the information above, PNEC values for freshwater, sediment, and soil were not derived for sodium hydroxide.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium hydroxide is an inorganic salt that dissociates completely to sodium and hydroxide ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and hydroxide ions are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable to this inorganic salt.

Sodium and hydroxide ions are essential to all living organisms, and their intracellular and extracellular concentrations are actively regulated. Thus, sodium hydroxide is not expected to bioaccumulate and does not meet the screening criteria for bioaccumulation.

No chronic toxicity data exist on sodium hydroxide; however, the acute EC_{50} values are > 1 mg/L in fish, invertebrates and algae. Thus, sodium hydroxide does not meet the screening criteria for toxicity.

The overall conclusion is that sodium hydroxide is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Metal Corrosive Category 1

Skin Corrosive, Category 1A

Eye Damage, Category 1

EU Concentration Limits:
≥ 5%: Skin Corrosive 1A
≥ 2 to <5%: Skin Corrosive 1B

≥ 0.5%to <2%: Skin Irritant Category 2
≥ 0.5% to <2%: Eye Irritant Category 2

In addition to the hazard statements corresponding the GHS classification for corrosive, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

C. Pictograms



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Flush with plenty of fresh water for 15 minutes holding eyelids open, lifting eyelids occasionally to ensure complete removal of the product. Remove contacts, if present and easy to do. DO NOT allow rubbing of eyes or keeping eyes closed. Seek medical attention.

Skin Contact

Rinse with soap and plenty of water for several minutes. Remove contaminated clothing. Seek medical attention immediately.

Inhalation

Remove person to fresh air. Apply artificial respiration if not breathing. Seek medical attention.

Ingestion

Rinse mouth with water (only if the person is conscious), but do not administer fluids. Do NOT induce vomiting. Seek medical attention immediately.

B. Fire Fighting Information

Extinguishing Media

Carbon dioxide, water spray, foam, dry chemical.

Specific Exposure Hazards

Containers may explode when heated. May form explosive mixtures with strong acids. Hazardous combustion products may include the following materials: halogenated compounds, metal oxides/oxides, sodium monoxide.

Special Protective Equipment for Firefighters

Full protective clothing and approved self-contained breathing apparatus required for firefighting personnel.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment and avoid direct contact. Do not touch damaged containers or spilt material unless wearing appropriate protective clothing. Ventilate the area before entry.

Environmental Precautions

Prevent spills from entering storm drains or sewers and contact with soil.

Steps to be Taken if Material is Released or Spilt

Use an absorbent material to recover as much product as possible, then rinse the affected area with water to dilute the residue. Disposal of leftover product and used containers should be carried out in accordance with all local, state and federal regulations.

D. Storage and Handling

General Handling

Wear appropriate personal protective equipment. Avoid contact with eyes, skin or clothing. Avoid breathing mist, vapours or spray. Use only with adequate ventilation. Wash hands after use. Launder contaminated clothing.

Storage

Store away from acids. Keep container closed when not in use. Store in a cool well-ventilated area.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

The workplace exposure standard for sodium hydroxide in Australia is 2 mg/m^3 as a peak limitation, with a sensitisation notation. A peak limitation is defined by Safe Work Australia as a maximum or peak airborne concentration of a substance determined over the shortest analytically practicable period of time which does not exceed 15 minutes.

Engineering Controls

Good general ventilation should be used. If applicable, use process enclosures, local exhaust ventilation or other engineering controls to maintain airborne levels below recommended exposure limits.

Personal Protection Equipment

Respiratory Protection: Use a mask or approved air-purifying respirator with appropriate cartridge or canister in spray applications or in confined spaces.

Hand Protection: Wear impervious gloves to prevent skin contact and absorption of this material. Rubber or Neoprene gloves may afford adequate skin protection.

Skin Protection: Wear appropriate clothes (i.e., coveralls). Use non-slip footwear.

Eye Protection: Wear eye protection in situations where splash or thick mists are possible.

Other Precautions: Avoid contact with skin, eyes and clothing. When using, do not eat or drink. Wash hands thoroughly with soap and water before eating or drinking. Remove contaminated clothing and launder before reuse.

F. Transport Information

For sodium hydroxide solutions of > 5%:
Australian Dangerous Goods
UN1824, Corrosive liquid, (Sodium hydroxide solution)
Class 8
Packing Group: II

Lower concentrations of sodium hydroxide may require a different packing group or may not require any hazard code if the concentration of NaOH is low enough not to be considered a corrosive material.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2011). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

De Groot et al. (2002). The addition of sodium hydroxide to a solution with sodium bicarbonate to a fixed pH. Solvay Pharmaceuticals Int. Doc. No. 8320/47/01; cited in OECD, 2002a,b.

Department of the Environment, Water, Heritage and the Arts (DEWHA). (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

Ganong, W.F. (1995). Review of Medical Physiology, 17th Edition, Appleton & Lange, Norwalk, Connecticut, USA.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regulatory Toxicology and Pharmacology 25:1-5.

Lide, D.R. (2009). Physical Constants of Inorganic Compounds. CRC Handbook of Chemistry & Physics, 89th Edition, CRC Press.

NIOSH. (1975). National Institute of Occupational Safety and Health: Criteria Document: Sodium Hydroxide p.46 (1975) DHEW Pub. NIOSH 76-105; cited in NICNAS IMAP assessment report for sodium hydroxide, https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessment-details?assessment_id=1406#cas-A_1310-73-2.

O'Neil, M.J. [Ed.]. (2006). The Merck Index - An Encyclopedia of Chemicals, Drugs, and Biologicals. P. 1485, Whitehouse Station, NJ: Merck and Co., Inc.

OECD. (2002a). IUCLID Data Set for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

OECD. (2002b). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium hydroxide (CAS No. 1310-73-2), UNEP Publications. Available at: http://webnet.oecd.org/Hpv/UI/SIDS_Details.aspx?id=DC48343F-5AEA-4850-9A17-0A89331E4320.

UNEP. (1995). Water quality of world river basins. UNEP Environment Library No. 14, Nairobi, Kenya; cited in OECD, 2002a,b.

SODIUM SULPHATE

This dossier on sodium sulphate presents the most critical studies pertinent to the risk assessment of sulphate in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained the OECD-SIDS documents on sodium sulphate (OECD, 2005a,b), and from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Disodium sulphate

CAS RN: 7757-82-6

Molecular formula: Na_2SO_4

Molecular weight: 142.04 g/mol

Synonyms: Sodium sulphate; disodium sulphate; sodium bisulphate; sulphuric acid, disodium salt

SMILES: [O-]S(=O)(=O)[O-].[Na+].[Na+]

II. PHYSICO-CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Sodium Sulphate

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White crystalline solid	2	ECHA
Melting Point	ca. 884°C (pressure not reported)	2	ECHA
Density	2700 kg/m^3 @ 20°C	2	ECHA
Partition Coefficient (Log K_{ow})	-4.38 (temperature not provided)	2	ECHA
Water Solubility	445.5 g/L @ 20°C	1	ECHA
Auto flammability	Not auto flammable	1	ECHA

III. ENVIRONMENTAL FATE SUMMARY

Sodium sulphate dissociates in aqueous media to sodium (Na^+) and sulphate (SO_4^{2-}) ions. Biodegradation is not applicable to inorganic compounds. Sodium sulphate is not expected to bioaccumulate; it will dissociate to ions that are ubiquitous in the environment. Sodium sulphate is not expected to adsorb to soil or sediment because of its dissociation properties and high water solubility.

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Sodium sulphate exhibits low acute toxicity by the oral and inhalation routes. It is not irritating to the skin and eyes; and it is not a skin sensitiser. In a reproductive and developmental toxicity screening study, there was no indication of any toxicity in rats given oral doses as high as 1,000 mg/kg/day. Sodium sulphate is not genotoxic.

B. Acute Toxicity

Oral

The oral LD_{50} in rats is > 2,000 mg/kg (ECHA) [KI score = 1].

Human data indicate a very low acute toxicity of sodium sulphate. High oral doses of sodium sulphate, from 300 mg/kg up to 20 grams for an adult, are well tolerated, except from (intentionally) causing severe diarrhea (OECD, 2005a,b).

Inhalation

The 4-hour inhalation LC_{50} for an aerosol of sodium sulphate is > 2.4 mg/L, which was the highest technically feasible aerosol concentration. The mass median aerodynamic diameters (MMAD) were 2.65 to 2.71 µm (ECHA) [KI score = 1].

Dermal

There is no data on acute dermal toxicity.

C. Irritation

Application of 0.5 g sodium sulphate (in PEG 400) to the skin of rabbits for 4 hours was not irritating (ECHA) [KI score = 1].

Instillation of 90 mg sodium sulphate to the eyes of rabbits was not irritating (ECHA) [KI score = 1].

D. Sensitisation

Sodium sulphate was not considered a skin sensitiser in a mouse local lymph node assay (ECHA) [KI score = 1].

E. Repeated Dose Toxicity

Oral

In a reproductive and developmental toxicity screening (OECD 421) study, male and female Wistar rats were dosed by oral gavage with 0, 100, 300 or 1,000 mg/kg sodium sulphate for a total of 4 weeks for males and 7 weeks for females. There was no evidence of toxicity at any dose level. The NOAEL for systemic toxicity is 1,000 mg/kg/day, the highest dose tested.

Inhalation

No studies are available.

Dermal

No studies are available.

F. Genotoxicity

In Vitro Studies

The *in vitro* genotoxicity studies on sodium sulphate are presented in Table 2.

Table 2: *In vitro* Genotoxicity Studies on Sodium Sulphate

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (S. typhimurium and E. coli strains)	-	-	1	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberration (Chinese hamster lung fibroblasts)	-	-	1	ECHA

*+, positive; -, negative

In Vivo Studies

No studies are available.

G. Carcinogenicity

No valid studies are available.

H. Reproductive/Developmental Toxicity

A reproductive and developmental toxicity screening (OECD 421) study has been conducted on sodium sulphate. Male and female Wistar rats were dosed by oral gavage with 0, 100, 300 or 1,000 mg/kg sodium sulphate. There were no deaths during the study and no clinical signs of reproductive or developmental toxicity at any dose level. Body weights, body weight gain and feed consumption were similar across all groups. The NOAEL for systemic, reproductive and developmental toxicity is 1,000 mg/kg/day, the highest dose tested (ECHA) [Kl score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

Toxicological reference values were not derived. Sodium sulphate dissociates in water to sodium and sulphate ions.

The Australian drinking water guideline value for sodium is 180 mg/L based on aesthetics (ADWG, 2021).

The Australian drinking water guideline value for sulphate is 500 mg/L based on health. Concentrations of > 500 mg/L can have purgative effects. There is also an Australian drinking water guideline value for sulphate of 250 mg/L based on aesthetics; it is the taste threshold (ADWG, 2021).

I. Cancer

There are no valid carcinogenicity studies on sodium sulphate. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Sodium sulphate does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

J. A. Summary

Sodium sulphate is of low acute concern to aquatic life.

K. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on sodium sulphate.

Table 3: Acute Aquatic Toxicity Studies on Sodium Sulphate

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Pimephales promelas	96-hour LC_{50}	7,960	2	Mount et al. (1997)
Daphnia magna	48-hour EC_{50}	4,736*	2	Davies and Hall (2007)

* Standard test conditions: 100 mg $CaCO_3$/L and Ca:Mg ratio of 0.7.

Chronic Studies

The 7-day LOEC from a *Ceriodapnia dubia* reproduction study, in which the test media contained varying degrees of water hardness, was 1,329 mg/L. The NOEC was extrapolated to be approximately 1,109 mg/L (Soucek, 2007).

L. Sediment Toxicity

The lowest 96-hour LC_{50} value to *Hyalella azteca* in a series of studies involving different hardnesses of water was 757 mg/L (Soucek and Kennedy, 2005). In another study with *Hyalella azteca*, the lowest 96-hour LC_{50} value (in water with the lowest hardness) was 841

mg/L (Davies and Hall, 2007). The lowest 96-hour LC_{50} value to *Chironomus tentans* in a series of studies involving different hardnesses of water was 20,899 mg/L (Soucek and Kennedy, 2005).

M. Terrestrial Toxicity

No adequate studies were located.

N. Calculation of PNEC

The PNEC calculations for sodium sulphate follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for two trophic levels. Acute E(L)C50 values are available for fish (7,960 mg/L) and *Daphnia* (4,736 mg/L). The NOEC from a chronic study on invertebrates was 1,109 mg/L. On the basis that the data consists of results from short-term studies from two trophic levels and a single long-term study, an assessment factor of 100 has been applied to the chronic NOEC value of 1,109 mg/L for invertebrates. The $PNEC_{water}$ is 11 mg/L.

PNEC sediment

No reliable experimental toxicity data on sediment organisms are available. Sodium sulphate dissociates completely in water with its environmental distribution is dominated by its high water solubility. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sediment}$. Based on its properties, no adsorption of sodium sulphate to sediment is to be expected, and the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

No reliable experimental toxicity data on terrestrial organisms are available. The environmental distribution of sodium sulphate is dominated by its water solubility. Sorption of sodium sulphate should probably be regarded as a reversible situation, i.e., the substance is not tightly nor permanently bound. K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as sodium sulphate. Thus, the equilibrium partitioning method cannot be used to calculate the $PNEC_{soil}$. Based on its properties, sodium sulphate is not expected to significantly adsorb to soil, and the assessment of this compartment will be covered by the aquatic assessment.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Sodium sulphate is an inorganic salt that dissociates completely to sodium and sulphate ions in aqueous solutions. Biodegradation is not applicable to these inorganic ions; both sodium and sulphate ions are also ubiquitous and are present in most water, soil and sediment. For

the purposes of this PBT assessment, the persistent criteria are not considered applicable to sodium sulphate or its dissociated ions.

Sodium and sulphate ions are essential to all living organisms and their intracellular and extracellular concentrations are actively regulated. Thus, sodium sulphate is not expected to bioaccumulate.

The NOEC from a chronic toxicity study with *Ceriodaphnoa rerio* is > 0.1 mg/L. The acute E(L)C_{50} values for fish and *Daphnia* are > 1 mg/L. Thus, sodium sulphate does not meet the criteria for toxicity.

Therefore, sodium sulphate is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Labelling

No signal words.

C. Pictogram

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. If symptoms persist, seek medical attention.

Skin Contact

Wash with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Do not induce vomiting. Rinse mouth with water and then drink a small amount of water. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

May emit toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: sodium and sulfur oxides.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Avoid creating and breathing dust.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop and remove.

D. Storage And Handling

General Handling

Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational standard for sodium sulphate.

Engineering Controls

Use in a well-ventilated area.

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium sulphate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods Code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Davies, T.D. and Hall, K.J. (2007). Importance of calcium in modifying the acute toxicity of sodium sulphate to hyalella Azteca and Daphnia magna. Environ. Toxicol. Chem. 26: 1243-1247.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Mount, D.R., Gulley, D.D., Hockett, J.R., Garrison, T.D., and Evans, J.M. (1997). Statistical models to predict the toxicity of major ions to Ceriodaphnia dubia, Daphnia magna and Pimephales promelas (Fathead minnows). Environ. Toxicol. Chem. 16: 2009-2019.

OECD. (2005a). Screening Information Dataset (SIDS) Initial Assessment Report for Sodium sulphate (CAS No. 7757-82-6), UNEP Publications.

OECD. (2005b). IUCLID Data Set for Sodium sulphate (CAS No. 7757-82-6), UNEP Publications.

Soucek, D.J. (2007). Comparison of hardness and chloride regulated acute effects of sodium sulphate on two freshwater crustaceans. Environ. Toxicol. Chem. 26: 773-779.

Soucek, D.J., and Kennedy, A.J. (2005). Effects of hardness, chloride, and acclimation on the acute toxicity of sulphate to freshwater invertebrates. Environ. Toxicol. Chem. 24: 1204-1210.

BORIC ACID (CAS NO. 10043-35-3)
SODIUM TETRABORATE DECAHYDRATE (BORAX) (CAS NO. 1303-96-4)

This dossier presents the most critical studies pertinent to the risk assessment of two boron compounds (boric acid and borax) in their use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): boric acid

CAS RN: 10043-35-3

Molecular formula: BH_3O_3

Molecular weight: 61.84 g/mol

Synonyms: orthoboric acid; boracic acid; borofax; boron hydroxide; boron trihydroxide

SMILES: B(O)(O)O

Chemical Name (IUPAC): disodium bicyclo[3.3.1]tetraboroxane-3,7-bis(olate)

CAS RN: 1303-96-4

Molecular formula: $B_4Na_2O_7$

Molecular weight: 381.4 g/mol

Synonyms: sodium tetraborate decahydrate; borax; monosodium metaborate; sodium borate; sodium borate (NaBO2); sodium diborate; sodium meta borate; sodium metaborate; sodium tetraborate

SMILES: B1(OB2OB(OB(O1)O2)[O-])[O-].O.O.O.O.O.O.O.O.O.O.[Na+].[Na+]

II. PHYSICAL AND CHEMICAL PROPERTIES

Limited measured data are available for borax. In the environment, borax is expected to dissociate and/or hydrolyse to release boric acid at neutral pH. Therefore, measured data available for boric acid have been presented as analogue data for this substance.

Key physical and chemical properties for boric acid are shown in Table 1.

Table 1: Overview of the Physico-chemical Properties of Boric Acid

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, odourless, crystalline solid	2	ECHA
Melting Point	> 100°C (decomposes)	1	ECHA
Boiling Point	Not Applicable	-	ECHA
Density	1,489 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure	0 Pa @ 25°C	1	ECHA
Partition Coefficient (log K_{ow})	Not Applicable, substance is inorganic	-	ECHA
Water Solubility	48.8 g/L @ 20°C	1	ECHA
Dissociation Constant (pKa)	8.94 @ 20°C	1	ECHA

Boron is almost exclusively found in the environment in the form of boron-oxygen (B-O) compounds, which are often referred to as borates. The high strength of the B-O bond relative to those between boron and other elements makes boron oxide compounds stable compared to nearly all non-oxide boron materials. Indeed, the B-O bond is among the strongest found in the chemistry of naturally occurring inorganic substances (ECHA).

In the environment, borates and compounds of boric acid will dissociate and/or hydrolyse to form the same boron species. For example, when borax dissolves in dilute solutions, it dissociates into Na^+ ions and the tetraborate anion ($B_4O_5(OH)_4^{2-}$). Boric acid ($B(OH)_3$) is formed following acid catalysed hydrolysis of the tetraborate anion. Under alkaline conditions, dilute solutions of the tetraborate anion depolymerise rapidly to the mononuclear borate anion ($B(OH)_4^-$) (NICNAS, 2019).

Boric acid is a Lewis acid that acts as a weak monoprotic acid by accepting OH^- and not as a proton donor (pKa 9.14). Therefore, at the near neutral pH of most environmental systems and at low concentrations (< 0.025 mol B/L), the neutral mononuclear species ($B(OH)_3$) will dominate and only a small proportion of boron will exist as the borate monoanion, $B(OH)_4^-$. Therefore, in the environment boric acid is in equilibrium with borate anions. Both species are very stable as they do not undergo biotransformation or redox reactions under normal environmental conditions (NICNAS, 2019).

Exposure to borates are often expressed in terms of boron (B) equivalents based on the fraction of boron in the source substance on a molecular weight basis. The B equivalents used are a generic designation rather than a designation of the element boron. The factor for converting boric acid to B-equivalents is 0.1748. The factor for converting borax to B-equivalents is 0.2149.

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Borax will transform into boric acid in the aquatic environment. In the environment boric acid is in equilibrium with borate anions. Degradation is not applicable to inorganic borates.

Boric acid is highly soluble in water. Some partitioning to soil and sediment does occur, but this adsorption is pH dependent. It has a low potential for bioaccumulation.

B. Partitioning

Borax will transform into boric acid in the aquatic environment. In the environment boric acid is in equilibrium with borate anions. Both species are very stable as they do not undergo biotransformation or redox reactions under normal environmental conditions. Boric acid is highly water soluble and it tends to remain in surface waters. Although some partitioning from water to soil and sediment does occur, the adsorption is pH dependent with the greatest adsorption occurring under alkaline conditions (pH 7.5 to 9.0) (NICNAS, 2019).

C. Biodegradation

Degradation is not applicable to inorganic borates. It is not subject to hydrolysis, photodegradation or biodegradation (ECHA). Inorganic borates are subject to chemical transformation processes (adsorption, complexation, precipitation, fixation) once released into the environment (ECHA).

D. Environmental Distribution

The Kp value for boron compounds was calculated as the median of all measured Kp values from the GEMAS project (Geochemical Mapping of Agricultural and Grazing Land Soil project): 2.19 L/kg dry weight (ECHA) [KI score = 2]. The chemistry of boron in soils and aquatic systems is simplified by the absence of oxidation-reduction reactions or volatilisation. Redox processes can mobilise Fe oxides and Mn oxides, which may lead to a release of boron in aquatic systems. Generally, sediments are characterised with higher pH values than the soil matrix, which increases the boron sorption capacity (ECHA).

If released to soil, based on this low Kp value, low vapour pressure and high water solubility, boric acid and borax are considered relatively mobile in the environment, under certain conditions (ECHA).

E. Bioaccumulation

The WHO review of boron (WHO, 1998) noted that “highly water soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as un-dissociated and highly soluble boric acid at neutral pH”. BCFs of < 0.1 to 10.5 L/kg have been reported from laboratory tests of fish and oysters (Hamilton and Wiedmeyer, 1990; Thompson et al., 1976).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Borax exhibits low acute toxicity by the oral and dermal routes. Boric acid exhibits low acute toxicity by the oral, dermal and inhalation routes. Neither substance is a skin or eye irritant, nor a skin sensitiser. In aqueous media at physiological pH, borax will predominantly exist as un-dissociated boric acid. The developing foetus and the testes are the two most sensitive targets of boron toxicity in multiple species. The testicular effects include reduced organ weight and organ to body weight ratio, atrophy, degeneration of the spermatogenic

epithelium, impaired spermatogenesis, reduced fertility and sterility. The developmental effects from boron exposure include high prenatal mortality, reduced foetal body weight, malformations and variations. Repeated inhalation exposure to read-across substance boron oxide resulted in slight irritation to the respiratory tract, but no systemic toxicity. Boric acid was not genotoxic, and boric acid and borax was not carcinogenic to rodents.

B. Toxicokinetics

Boric acid is not metabolised in either animals or humans, owing to the high energy level required (523 kJ/mol) to break the B-O bond. Other inorganic borates convert to boric acid at physiological pH in the aqueous layer overlying the mucosal surfaces prior to absorption. Most of the simple inorganic borates exist predominantly as undissociated boric acid in dilute aqueous solution at physiological and environmental pH, leading to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under the same conditions. Additional support for this derives from studies in which more than 90% of administered doses of inorganic borates are excreted in the urine as boric acid. Absorption of borates via the oral route is nearly 100%. For the inhalation route also, 100% absorption is assumed as worst-case scenario. Dermal absorption through intact skin is very low with a percent dose absorbed of 0.226 ± 0.125 in humans. Using the % dose absorbed plus standard deviation (SD) for boric acid, a dermal absorption for borates of 0.5% (rounded from 0.45%) can be assumed as a worse-case estimate (ECHA).

In the blood boric acid is the main species present and is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2 to 3 times higher than in other tissues. Boric acid is excreted rapidly, with elimination half-lives of 1 hour in the mouse, 3 hours in the rat and < 27.8 hours in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine (ECHA).

C. Acute Toxicity

The oral LD_{50} of borax in rats is > 2,500 mg/kg (ECHA) [KI score = 1]. The oral LD_{50} of boric acid in rats is 3,450 mg/kg (ECHA) [KI score = 1].

There are no acute inhalation studies on borax. In a read-across study for borax, the 4-hour inhalation LC_{50} value for disodium tetraborate pentahydrate in rats is > 2.04 mg/L (ECHA) [KI score = 1]. The 4-hour inhalation LC_{50} value for boric acid in rats is > 2.01 mg/L. The mass median aerodynamic diameter (MMAD) was 2.8 µm (ECHA) [KI score = 1]. In another study, the 4-hour inhalation LC_{50} value for boric acid in rats was > 2.03 mg/L (ECHA) [KI score = 1].

The dermal LD_{50} of borax in rabbits is > 2,000 mg/kg (ECHA) [KI score = 2]. The dermal LD_{50} of boric acid in rabbits is > 2,000 mg/kg (ECHA) [KI score = 1].

D. Irritation

Application of 0.5 g of borax to the skin of rabbits for 4 hours under occlusive conditions was not irritating. The mean erythema and oedema scores were 0.00 (ECHA) [KI scores = 2]. Application of 0.5 g. of boric acid to the skin of rabbits for 24 hours under occlusive conditions was not irritating. The mean of the 24 and 72-hour scores were 0.13 for erythema and 0.00 for oedema (ECHA) [KI scores = 1].

Disodium tetraborates are eye irritants. Instillation of 0.08 mL of read-across substance disodium tetraborate pentahydrate into the eyes of rabbits was slightly irritating. The mean of 24, 48, and 72 hours scores were 0.22 for corneal opacity; 0.22 for iridial lesions; 2.8 for conjunctival redness; and 1.89 for chemosis. The effects were fully reversible (ECHA) [Kl score = 1].

Boric acid induced mild conjunctivae redness and chemosis and minor effects on the iris. The effects were reversible within 7 days (ECHA). Instillation of 100 mg of boric acid into the eyes of rabbits was slightly irritating. The mean of 24, 48, and 72-hour scores were 0.00 for corneal opacity; 0.11 for iridial lesions; 0.94 for conjunctival redness; and 0.56 for chemosis (ECHA) [Kl score = 1].

E. Sensitisation

There are no skin sensitisation studies on Borax. Read-across substances disodium tetraborate pentahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1].

Boric acid was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1]. Sodium tetraborate pentahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1]. Sodium tetraborate decahydrate was not a skin sensitiser to guinea pigs in a Buehler test (ECHA) [Kl score = 1].

F. Repeated Dose Toxicity

<u>Oral</u>

Male and female SD rats were given in their feed boric acid at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg/day, respectively (USEPA, 2004). By week 6, all animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen ovary and adrenal weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes and adrenal weights. The adrenals of 4 of the 1,750 ppm males showed minor increases in lipid content and size of the cells in the zona reticularis. Atrophied testis (complete atrophy of the spermatogenic epithelium and decreased in the size of the seminiferous tubules) was seen in all of the 1,750 ppm males. One 525 ppm male had partial testicular atrophy. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

Male and female SD rats were given in their diet borax at doses of 0, 52.5, 175, 525, 1,750 or 5,250 ppm B equivalents for 90 days. The average intake has been estimated to be approximately 0, 2.6, 8.8, 26, 87.5 or 262.5 mg B/kg/day, respectively (USEPA, 2004). By week 6, all the animals in the highest dose died. Clinical signs in the top two dose levels were rapid respiration, inflamed eyes, swollen paws and desquamated skin on the paws and tails. There was also reduced food consumption and body weight gain. The 1,750 ppm females showed reduced liver, spleen and ovary weights; the 1,750 ppm males showed reduced liver, spleen, kidney, testes and brain weights. The adrenals of the majority of the 1,750 ppm males and females showed slight to moderate increases in lipid content and size of the cells in the zona reticularis. Atrophied testis (complete atrophy of the spermatogenic epithelium

and decreased in the size of the seminiferous tubules) was seen in all the 1,750 ppm males. Four 525 ppm males had partial testicular atrophy. Spermatogenic arrest was found in one 525 ppm male. The NOAEL for this study is 175 ppm boron or 8.8 mg B/kg/day (Weir and Fisher, 1972) [KI score = 2].

Male and female B6CF1$_1$ mice were given in the diet 0, 1,200, 2,500, 5,000, 10,000 or 20,000 ppm boric acid for 13 weeks (control and highest dose group) or 16 weeks (remaining dose groups). These dietary levels correspond to approximately 0, 34, 70, 141, 281 and 563 mg B/kg/day for males, respectively: and 0, 47, 97, 194, 388 and 776 mg B/kg/day for females, respectively (USEPA, 2004). There was mortality (8/10 males; 6/10 females) in the 20,000 ppm group, as well as hyperkeratosis and acanthosis. One male also died in 10,000 ppm group. Degeneration or atrophy of the seminiferous tubules occurred in the ≥ 5,000 ppm males. Minimal to mild extramedullary haematopoiesis of the spleen was observed in all dose groups. The LOAEL for this study is 1,200 ppm, corresponding to 34 and 47 mg B/kg/day for males and females, respectively (NTP, 1987) [KI score = 2].

Male and female SD rats were given in their diet 0, 117, 350 or 1,170 ppm boric acid for two years. The average intake has been estimated to be approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively (USEPA, 2004). The 1,170 ppm rats had decreased food consumption during the first 13 weeks of the study and suppressed growth throughout the study. Signs of toxicity in the 1,170 ppm animals included swelling and desquamation of the paws, scaly tails, inflammation of the eyelids and bloody discharge from the eyes. All the 1,170 ppm males had testicular atrophy at the 6, 12 and 24-month time points. The seminiferous epithelium was atrophied, and the tubular size in the testes was decreased. There were significant decreases in the absolute and relative testes weights. Brain and relative thyroid weights were increased. The NOAEL for this study is 350 ppm B equivalents or 17.5 mg B/kg/day (Weir and Fisher, 1972) [KI score = 2].

Male and female B6C3F$_1$ mice were given up to 20,000 ppm boric acid in their feed for 13 weeks (NTP, 1987). Eight out of the 10 males and 6 out of the 10 females from the 20,000 ppm group died and 1 of the 10 males from the 10,000 ppm group died before the end of the study. Symptoms included nervousness, haunched appearance, dehydration, foot lesions and scaly tails. Incidences of extra medullary haematopoiesis of the spleen were observed of varying severity in all dose groups for both males and females and hyperkeratosis and/or acanthosis of the stomach observed at the highest dose only in both males and females. At doses > 5,000 ppm (142 mg B/kg bw for the male), degeneration or atrophy of the seminiferous tubules was observed. The NOAEL for this study is 34 mg B/kg/day (NTP, 1987) [KI score = 2].

Inhalation

Male and female rats were exposed by inhalation to 0, 77, 175 or 470 mg/m^3 boron oxide. The exposures were 6 hours/day, 5 days/week for 24, 12, and 10 weeks for the 77, 175, and 470 mg/m^3 concentrations groups, respectively. The MMAD were 2.5, 1.9 and 2.4 µm for the 77, 175 and 479 mg/m^3 concentrations groups, respectively. There was no evidence of systemic toxicity. Some of the 470 mg/m^3 had reddish exudate from the nose. As these animals were covered with dust, this effect may have been local irritation of the nose and from the animals scratching the nose. The NOAEL for systemic toxicity is 470 mg/m^3, the highest exposure concentration tested. The NOAEL for localised effects (irritation) is 175 mg/m^3 (ECHA) [KI score = 2].

Dermal

No studies are available.

G. Genotoxicity

In Vitro Studies

There are no *in vitro* genotoxicity studies on borax. Table 2 presents the results of the *in vitro* genotoxicity studies on boric acid.

Table 2: *In vitro* Genotoxicity Studies on Boric Acid

Test System	Results*		Klimisch Score	Reference
	-S9	+S9		
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	1	ECHA
Bacterial reverse mutation (*S. typhimurium* strains)	-	-	2	ECHA
Mammalian cell gene mutation (mouse lymphoma L5178Y cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations (Chinese Hamster Ovary cells)	-	-	1	ECHA
Chromosomal aberrations (Human peripheral lymphocytes)	NS	+	2	ECHA
Unscheduled DNA synthesis (rat liver cells)	NA	-	1	ECHA

*+, positive; -, negative; NA, not applicable; NS, not specified.

In Vivo Studies

No studies are available on borax.

Male and female Swiss Webster mice were given two daily doses of 0, 225, 450, 900, 1,800 or 3,500 mg/kg boric acid. The frequency of micronucleated polychromatic erythrocytes were not increased at any dose level (ECHA) [KI score = 1].

H. Carcinogenicity

Oral

Male and female SD rats were given in their diet disodium tetraborate decahydrate (Borax) or boric acid at doses of 0, 117, 350 or 1,170 ppm as B equivalents (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day) for two years. There was no mention of tumours in the report. Nevertheless, NTP (1987) concluded that this study provided adequate data on the lack of carcinogenic effects of boric acid in rats (Weir and Fisher, 1972; USEPA, 2004).

Male and female B6C3F_1 mice were given in their diet 0, 2,500 or 5,000 ppm boric acid for 103 weeks. The dietary levels are equivalent to 0, 446 or 1,150 mg/kg/day boric acid or 0,

78.1 or 201.3 mg B/kg/day. There was no evidence of carcinogenicity (NTP, 1987) [Kl score = 2].

I. Reproductive Toxicity

A three-generation reproductive toxicity study was conducted in Sprague-Dawley rats with boric acid. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation and appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170-ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

A three-generation reproductive toxicity study was conducted in Sprague-Dawley rats with borax. Male and female rats were fed a diet containing 0, 117, 350 or 1,170 ppm boron (approximately 0, 5.9, 17.5 or 58.5 mg B/kg/day, respectively). In the lower two dose groups, there were no treatment-related effects on reproduction. Litter size, progeny weights, fertility, live birth indices, lactation, appearance were similar to the controls. No gross abnormalities were noted in these two dose groups. The 1,170-ppm dose group were found to be sterile, and there were no litters from mating the treated females with control males. Lack of viable sperm was found in the atrophied testes of all 1,170 ppm males. Decreased ovulation was also seen in the majority of the ovaries of the 1,170 ppm females. The NOAEL for this study is 350 ppm boron or approximately 17.5 mg B/kg/day (Weir and Fisher, 1972) [Kl score = 2].

In a continuous breeding protocol, male and female CD-1 mice were given in their diet 0, 1,000, 4,500 or 9,000 ppm boric acid in their feed. The authors estimated that the average daily intakes were 0, 26.6, 111 and 220 mg B/kg/day to males; and 0, 31.8, 152 and 257 mg B/kg/day to females. Boric acid consumption did not differ among the groups. There were no litters in the 9,000 ppm breeding pairs. At 4,500 ppm, there was a successful first litter, after which there was a progressive decrease in fertility; only one pair produced a fourth and fifth litter. All fertility indices were affected in the 4,500 ppm group. A complete crossover mating trial was conducted using control mice and the 4,500 ppm mice. The results showed that the probable cause of the reduced fertility was a decrement in male fertility. A dose-related decrease in body, testicular and epididymal weights was observed in the 4,500 and 9,000 ppm F_0 males. Sperm count was significantly decreased in these two dose groups, and percent motile sperm was decreased in all dose groups. Testicular histopathology showed seminiferous tubular atrophy in the 9,000 ppm males and partial atrophy of the seminiferous tubules in the 4,500 ppm males. There were no histopathologic changes in the 4,500 ppm females. No statistically significant decreases in mating index, fertility index or live pups/litter in the 4,500 ppm females, but the number of days to litter in this dose group was increased. Oestrous cyclicity was unaffected. Reproductive organ weights were unaffected, but relative maternal liver and kidney/adrenal weights were reduced. An F_1 fertility trial was performed using offspring from the 1,000 ppm groups. There were no decreases in mating, fertility or reproductive performance. The F_2 adjusted live pup weight was slightly, but significantly, reduced from controls. A clear NOAEL for reproductive toxicity in males was not seen in this study. The 1,000 ppm males had decreased sperm motility in

the F_0 generation and decreased sperm concentration in the F_1 generation. Decreased F_2 pup relative body weight was statistically significant from controls. The NOAEL in this study for females is 1,000 ppm boric acid or 32 mg B/kg/day). The LOAEL in this study for males is 1,000 ppm or 27 mg B/kg/day; a NOAEL was not established (Fail et al*.,* 1991) [Kl score = 2].

J. Developmental Toxicity

No studies are available on borax.

Pregnant female SD rats were given 0, 0.1, 0.2 or 0.4% boric acid in their feed on gestational days (GD) 0 to 20 or 0.8% boric acid on GD 6 to 15. The average amounts of boric acid ingested were estimated to be 0, 78, 163, 330 or 539 mg/kg/day (0, 13.6, 28.5 or 57.7 mg B/kg/day), respectively. Effects on the pregnant rats were altered food and/or water intake at ≥ 0.2% boric acid, increased liver and kidney weights relative to body weights at ≥ 0.2%, reduced weight gain at ≥ 0.4%, and increased corrected weight gain at 0.4% boric acid. There was a reduction in foetal body weights in all treated groups (94, 87, 63 and 47% of control weight, respectively). Increased malformations occurred at ≥ 0.2%, and prenatal mortality was increased at 0.8%. There was a dose-response for altered skeletal morphology in rats (≥ 0.1%), and specific findings were significantly elevated above controls at ≥ 0.2%. Specifically, there was an increased incidence of short rib XIII (a malformation) and a decreased incidence or rudimentary or full rib(s) at lumbar I (an anatomical variation) (Heindel et al., 1992) [Kl score = 2].

Pregnant female SD rats were given in their feed 0, 0.025, 0.005, 0.075, 0.1 or 0.2% boric acid on GD 0 to 20. Approximately half of the dams were terminated on GD 20, and the remaining dams delivered their litters. Pup growth and viability were monitored until postnatal day (PND) 21. The average amounts of boron ingested on GD 20 were: 0, 3.3, 6.3, 9.6, 13.3 and 25 mg B/kg/day, respectively. The average amounts of boron ingested on PND 21 were 0, 3.2, 6.5, 9.7, 12.9 and 25.3 mg B/kg/day, respectively. There were no maternal deaths and no treatment-related clinical signs. Maternal body weights were similar across all groups during gestation. However, decreased maternal body weights (GD 19 and 20 at sacrifice) and decreased maternal body weight gain (GD 15-18 and GD 0-20) were statistically significant in trend tests. There was a 10% reduction in gravid uterine weight (statistically significant) in the 0.2% group. Corrected maternal weight (maternal gestational weight minus reduced gravid uterine weight) was unaffected by treatment. Feed intake in the 1,000 ppm dams was minimally affected and only during the first three days of dosing. Water consumption was higher in the treated groups after GD 15. The number of corpora lutea and uterine implantation sites, and the percentage of preimplantation loss were similar across all groups. Increased relative kidney weights were increased in the 0.2% group. There were no differences in the viability of the offspring between treated and controls. On GD 20, foetal body weight was 94% and 88% of controls in the 0.1% and 0.2% groups, respectively; recovery was complete at birth (~GD 22). The incidence of short rib XIII was increased on GD 20 in the ≥ 0.1% groups, but only in the 0.2% group at PND 21. The incidence of wavy rib was increased on GD 20 in the ≥ 0.1% group; the reversibility of this effect was confirmed on PND 21. There was a slight decrease in extra lumbar ribs in the 0.2% group on GD 20, and extra lumbar ribs were seen in the 0.2% group on PND 21. The developmental NOAEL was considered to be 0.075% boric acid or 9.6 mg B/kg/day on GD 20; and 0.1% boric acid or 12.9 mg B/kg/day on PND 21 (Price et al., 1996a) [Kl score = 1].

Pregnant Swiss mice were given in their diet 0, 0.1, 0.2 or 0.4% boric acid on gestational days (GD) 0 to 17. The average amounts of boric acid ingested were estimated to be 248, 452 or

1,003 mg/kg/day (0, 43.4, 79.0 or 175.3 mg/B/kg/day), respectively. Maternal toxicity consisted of mild kidney lesions (≥ 0.1%), increased water intake and relative kidney weights (0.4%), and decreased water intake during treatment. Foetal body weights were reduced in the ≥ 0.2% groups, and there were increased incidences of resorptions and malformed foetuses per litter in the 0.4% group. The LOAEL for maternal toxicity is 248 mg/kg/day boric acid or 43.4 mg B/kg/day; a NOAEL was not established. The NOAEL for developmental toxicity is 248 mg/kg/day boric acid or 43.4 mg B/kg/day (Heindel et al., 1992) [KI score = 2].

Pregnant female New Zealand rabbits were dosed by oral gavage with 0, 62.5, 125 or 250 mg/kg boric acid (0, 10.9, 21.9 or 43.7 mg B/kg) during GD 6-19. Feed intake was in the 250 mg/kg maternal animals during the exposure period, but it was increased in the ≥ 125 mg/kg dose groups. In the 250 mg/kg group, maternal body weights during GD 9-30, weight gain during GD 6-19, gravid uterine weight and number of corpora lutea per dam were significantly reduced. In the ≥ 125 mg/kg groups, maternal corrected gestational weight gain was increased compared to controls. Maternal liver weights were unaffected by treatment. In the 250 mg/kg group, relative, but not absolute, kidney weights were increased, although no effects in the kidney were noted in the histopathological examination. Prenatal mortality was increased in the 250 mg/kg group (90% resorptions/litter versus 6% for controls); the proportion of pregnant females with no live foetuses was increased (73% versus 0%), and live litter size was reduced (2.3 foetuses versus 8.8). Thus, there were only 14 live foetuses (6 live litters) available for evaluation in the 250 mg/kg group. The percentage malformed foetuses/litter was increased in the 250 mg/kg group, primarily due to cardiovascular defects (72% versus 3% of controls). There was no definitive maternal or developmental toxicity in the 62.5 or 125 mg/kg dose groups. The NOAEL for maternal and developmental toxicity is 125 mg/kg/day boric acid or 21.9 mg B/kg/day (Price et al., 1996b) [KI score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for boric acid follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021)).

A. Non-Cancer

An oral reference dose was not derived for boric acid or borax.

The Australian drinking water guideline value for boron (4 mg/L) may be applicable (ADWG 2011 updated 2021). The health-based ADWG value was based on a tolerable daily intake (TDI) of 0.16 mg/kg bw. This TDI is based on the NOAEL of 9.6 mg/kg/bw/day for foetal bodyweight effects in a rat developmental study (Price et al., 1996a) with an uncertainty factor of 60 (10 for interspecies and 6 for human intraspecies).

B. Cancer

There was no evidence of carcinogenicity in rat and mouse chronic studies conducted on borax and/or boric acid. Thus, a cancer reference value was not derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Borax and boric acid do not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Borax and boric acid have low acute and chronic toxicity to aquatic organisms.

B. Aquatic Toxicity

In ecotoxicological tests for boron, the exposure concentrations are expressed as boron equivalents, i.e., mg B/L. This is because boric acid and borate salts will have the same boron speciation when dissolved in environmental matrices. Therefore, in the following sections toxicological values are given as mg B/L regardless of the form of boron that was tested.

Acute Studies

Borax will transform into boric acid in the aquatic environment. Table 3 lists the results of acute aquatic toxicity studies conducted on boric acid.

Table 3: Acute Aquatic Toxicity Studies on Boric Acid

Test Species	Endpoint	Results (mg B/L)	Klimisch score	Reference
Fathead minnow	96-hour LC_{50}	79.7	2	ECHA
Legumia recta (Black sandshell mussel)	96-hour LC_{50}	147	2	ECHA
Hyalella azteca	96-hour LC_{50}	64	2	ECHA
Pseudokirchneriella subcapitata	72-hour EC_{50}	52.4 mg B/L	1	ECHA

Chronic Studies

Long-term effects (LC_{10}) on freshwater fish ranged from 3.5 to 47 mg B/L. Adequate long-term LC_{10} of 21.6 mg B/L was found for the freshwater fish *P. promelas* in a study according to USEPA OPPTS 850.1400 (ECHA) [Kl score = 2].

Long-term effects (LC_{10}/NOEC) on reproduction on freshwater vertebrates ranged from 6.6 to 32 mg B/L based on several well-accepted guideline studies (ECHA) [Kl scores =1 or 2].

Boric acid has been evaluated for its toxicity towards the freshwater alga *Pseudokirchneriella subcapitata* (formerly *Selenastrum capricornutum*) in an Alga growth inhibition test according to OECD 201 under GLP requirements. The exposure duration was 72 hours under static conditions. The NOEC growth rate determined from the study was 17.5 mg B/L (ECHA) [Kl score = 1].

The ANZG water quality guideline (2021) derived a very high reliability default guideline value (DGVs) for (dissolved) boron in freshwater from 22 chronic (long-term) toxicity data, comprising eight fish, two amphibians, three crustaceans, one bivalve, three macrophytes, one green microalga, three diatoms and one blue–green alga. The summary of representative data used by ANZG to develop a water quality guideline for boron is presented in Table 4. These values are noted to be consistent with those reported in ECHA. Additional chronic aquatic toxicity data is found in the ANZG Technical Brief (ANZG, 2021).

Table 4: Chronic Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg B/L)
Danio rerio	34-day NOEC (Biomass)	1.8
*Pimephales promela*s	32-day NOEC (Mortality)	11
Daphnia magna	14-day NOEC (Reproduction)	2.4
Pseudokirchneriella subcapitata	4-day NOEC (Growth)	2.8

1 - The DGVs are based on toxicity data for boron as either boric acid, H_3BO_3 (CAS 10043-35-3), or borax, $Na_2B_4O_710H_2O$ (CAS 1303-96-4), in freshwater.

In the chronic toxicity data set, fish sensitivity to boron ranged from the least sensitive species in the dataset (*Melanotaenia splendida*, LC_{10} 102 mg/L) to the third most sensitive species in the dataset (*Danio rerio*, NOEC 1.8 mg/L). Of the crustaceans, *D. magna* was best represented in the literature, with 18 published NOEC values (ranging from 2.4 mg/L to 29 mg/L) for six different endpoints from six different publications. The final NOEC of 2.4 mg/L used in the DGV derivation was lower than that for *C. dubia* (NOEC 5.6 mg/L) and for the amphipod *H. azteca* (NOEC 6.6 mg/L). For *P. subcapitata*, there were three separate studies available with toxicity data for boron. The toxicity values from these studies ranged from a NOEC of 2.8 mg/L to a NEC of 27 mg/L, varying with endpoint, duration and test medium used. Boron was least toxic to *P. subcapitata* when tested in algal growth medium with added $NaHCO_3$, suggesting that carbonate addition may have influenced boron toxicity. Therefore, although NECs are preferred to NOECs or EC10s, in this instance, a reliable NOEC of 2.8 mg/L was the most sensitive toxicity value for *P. subcapitata* (ANZG, 2021).

C. Sediment Toxicity

Limited sediment toxicity data are available for boric acid and boron containing compounds in general (NICNAS, 2019).

Chronic toxicity values for the effects of boric acid on sediment-dwelling invertebrates have been obtained for a freshwater midge (*Chironomus riparius*, harlequin fly), a freshwater bivalve (*Lampsilis siliquoidea*, fatmucket clam) and the aquatic worm (*Lumbriculus variegatus,* California blackworm). The respective toxicity values for these species are as follows: 28-day NOEC = 37.8 mg B/kg; 21-day LC_{25} (survival) = 363.1 mg B/kg; and 28-day NOEC = 100.8 mg B/kg (NICNAS, 2019).

Due to the high water solubility of boron and its low partitioning to sediment, sediment toxicity testing for boron is particularly challenging as it is difficult to ensure that exposure is through the solid phase (i.e., sediment) and not from the aqueous boric acid in the overlying water (NICNAS, 2019).

D. Terrestrial Toxicity

Ecotoxicological tests with plants and soil invertebrates have recorded modest chronic toxicity values (NOECs/ECs) in the range of 15.3 to 84.0 and 5.2 to 315 mg total B/kg, respectively (ECHA, 2008). However, to predict the potential toxicity of boron to plants and soil organisms, measuring the total boron concentration may be unsuitable. Instead, potential toxicity is better predicted using boron concentrations in the soil solution (extractable boron) (Mertens et al., 2011). In Australia, it is generally accepted that boron toxicity will pose a risk to terrestrial plants when soil concentrations exceed 15 mg/kg of extractable boron (NICNAS, 2019).

E. Calculation of PNEC

PNEC water

The ANZG water quality guideline (2021) derived a very high reliability DGV for (dissolved) boron in freshwater. The DGVs for 99, 95, 90 and 80% species protection are 340 µg/L, 940 µg/L, 1,500 µg/L and 2,500 µg/L, respectively. The 95% species protection level for boron in freshwater (940 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems (ANZG, 2021).

PNEC sediment

Limited sediment toxicity data are available for boric acid and boron containing compounds in general (NICNAS, 2019). Due to the high water solubility of boron and its low partitioning to sediment, sediment toxicity testing for boron is particularly challenging as it is difficult to ensure that exposure is through the solid phase (i.e., sediment) and not from the aqueous boric acid in the overlying water (NICNAS, 2019). K_{ow} and K_{oc} parameters do not readily apply to inorganics, such as boric acid and borax. Therefore, the equilibrium partitioning method cannot be used to calculate the $PNEC_{sed}$. As a result, the assessment of this compartment will be covered by the aquatic assessment.

PNEC soil

In the ECHA REACH database (ECHA), a $PNEC_{soil}$ was derived for boron using the species sensitivity distribution method and an assessment factor of 2. The $PNEC_{soil}$ was determined to be 5.7 mg/kg soil dry weight.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Borax is an inorganic compound that dissociates completely to boric acid and the borate anion in aqueous media. Biodegradation is not applicable to these inorganic compounds; both boric acid and borate are also ubiquitous and are present in most water, soil and sediment. For the purposes of this PBT assessment, the persistent criteria are not considered applicable.

A BCF of < 0.1-10.5 L/kg has been reported for borates in fish and oysters. This data suggests that boric acid does not bioaccumulate in the aquatic environment. Thus, boric acid and borax do not meet the criteria for bioaccumulation.

The chronic toxicity data on boric acid has a NOEC > 0.1 mg/L. Acute E(L)C_{50} values are > 1 mg/L. Thus, borax and boric acid do not meet the criteria for toxicity.

The overall conclusion is that borax and boric acid are not PBT substances.

IX. CLASSIFICATION AND LABELLING

A. Classification

Acute Toxicity Category 4 [Inhalation]

Eye Damage Category 1

Reproductive Toxicant Category 1B

STOT SE Category 3 [Respiratory irritation]

In addition to the hazard statements corresponding the GHS classifications, the following non-GHS hazard statement is to be added to the SDS: AUH071: Corrosive to the Respiratory Tract.

B. Labelling

Danger

According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child, causes serious eye damage, is harmful if swallowed, is harmful if inhaled, is suspected of damaging fertility or the unborn child, may cause respiratory irritation and causes skin irritation.

C. Pictogram



X. HANDLING AND SAFETY INFORMATION (OCCUPATIONAL LIMITS AND TRANSPORTATION REQUIREMENTS)

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water. Do not induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

None identified.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Use personal protective clothing. Avoid dust formation. Ensure adequate ventilation. Do not breathe dust. Wear respiratory protection if ventilation is inadequate. Avoid contact with skin, eyes and clothing.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage and Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Do not store with alkalis, acids or reducing agents.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for sodium perborate tetrahydrate.

Engineering Controls

Ensure adequate ventilation. Localised ventilation should be used to control dust levels below permissible exposure limits.

Personal Protection Equipment

Respiratory Protection: Use respiratory protection when airborne concentrations are expected to be high.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye Protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Sodium tetraborate decahydrate is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

ANZG. (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Fail, P.A., George, J.D., Seely, J.C., Grizzle, T.B., and Heindel, J.J. (1991). Reproductive toxicity of boric acid in Swiss (CD-1) mice: assessment using the continuous breeding protocol. Fundam. Appl. Toxicol. 17: 225-239.

Hamilton, S.J., and Wiedmeyer, R.H. (1990). Concentrations of boron, molybdenum and selenium in chinook salmon. Trans. Amer. Fisheries Soc. 119: 500-510.

Heindel, J.J., Price, C.J., Field, E.A., Marr, M.C., Myers, C.B., Morrissey, R.E., and Schwetz, B.A. (1992). Developmental toxicity of boric acid in mice and rats. Fundam. Appl. Toxicol. 18: 266-272.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Mertens, J., Van Laer, L. and Salaets, P. (2011). Phytotoxic doses of boron in contrasting soils depend on soil water content. Plant Soil. 342:73-82.

National Toxicology Program [NTP]. (1987). Toxicology and Carcinogenesis Studies of Boric Acid (CAS No. 10043-35-3) in $B6C3F_1$ Mice. NTP TR 324, NIH Publication No. 88-2580. National Toxicology Program, U.S. Department of Health and Human Services, National Institute of Health.

NICNAS. (2019). Boric acid and precursors to boric acid: Environment tier II assessment. Available on-line: https://www.industrialchemicals.gov.au/sites/default/files/Boric%20acid%20and%20precursors%20to%20boric%20acid_%20Environment%20tier%20II%20assessment.pdf

Price, C.J., Strong, P.L., Marr, M.C., Myers, C.B., and Murray, F.J. (1996a). Developmental toxicity NOAEL and postnatal recovery in rats fed boric acid during gestation. Fundam. Appl. Toxicol. 32: 179-193.

Price, C.J., Marr, M.C., Myers, C.B., Seely, J.C., Heindel, J.J., and Schwetz, B.A. (1996b). The developmental toxicity of boric acid in rabbits. Fundam. Appl. Toxicol. 34: 176-187.

Thompson, J.A., David, J.C. and Drew, R.E.(1976). Toxicity, uptake and survey studies of boron in the marine environment. Water Research. 10(10): 869-875.

USEPA. (2004). U.S. EPA (United States Environmental Protection Agency). Integrated Risk Information System (IRIS) – Boron and Compounds; CASRN 7440-42-8. Available at: http://www.epa.gov/iris.

Warner et al. (2018). Revised Method for Deriving Australian and New Zealand Water Quality Guideline Values for Toxicants – update of 2015 version. Prepared for the revision of the Australian and New Zealand Guidelines for Fresh and Marine Water Quality. Australian and New Zealand Governments and Australian state and territory governments, Canberra, 48 pp.

Weir, R.J., Jr., and Fisher, R.S. (1972). Toxicologic studies on borax and boric acid. Toxicol. Appl. Pharmacol. 23: 351-364.

WHO. (1998). Environmental Health Criteria 204, Boron, International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland

ULEXITE

This dossier on ulexite presents the most critical studies pertinent to the risk assessment of ulexite in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Sodium-calcium pentaborate octahydrate

CAS RN: 1319-33-1

Molecular formula: $(NaCaB_5O_6(OH)_6 \bullet 5H_2O)$

Molecular weight: 405 g/mol

Synonyms: Ulexite; sodium-calcium pentaborate octahydrate

Smiles: B1(OB2OB(O1)OB(O2)OB([O-])[O-])[O-].O.O.O.O.O.O.O.O.[Na+].[Ca+2]

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Commercially Available Ulexite

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	White, granular, ground or powder form	4	Etimine USA, Inc. (2016)
Melting Point	870°C	4	Etimine USA, Inc. (2016)
Boiling Point	Not Applicable	-	-
Bulk Density	1,410 to 1,500 kg/m^3	4	Etimine USA, Inc. (2016)
Water solubility	26.67% as dissolved Ulexite @ 25°C by weight of solution	4	American Borate Company (2016)

Ulexite is a naturally-occurring mineral that is slightly soluble in water. Limited measured data are available for ulexite. In a study investigating the relative rates of boron from soluble and controlled-release boron fertilizers, ulexite showed releases of boron of 20% in just under 10 weeks; 40% in approximately 25 weeks; 60% by 40 weeks; and 80% by 60 weeks (Broschat, 2008). In the environment, borates will dissociate and/or hydrolyse to release boron as boric acid [$B(OH)_3$ (also formulated as H_3BO_3)] and/or borate anions. Therefore, the information presented within this dossier is for boron (CAS No. 7440-42-8).

III. ENVIRONMENTAL FATE PROPERTIES

Boron is found almost exclusively in the environment in the form of boron-oxygen compounds, which are often referred to as borates. In the environment, borates and compounds of boric acid will dissociate and/or hydrolyse to form the same boron species. For example, when borax dissolves in dilute solutions, it dissociates into Na+ ions and the tetraborate anion ($B_4O_5(OH)_4^{2-}$). Boric acid ($B(OH)_3$) is formed following acid catalysed hydrolysis of the tetraborate anion. Under alkaline conditions, dilute solutions of the tetraborate anion depolymerise rapidly to the mononuclear borate anion ($B(OH)_4^-$) (DoEE, 2017).

Boron is an inorganic, elemental compound and can therefore not be biodegraded by micro-organisms or other biotic-related processes (ECHA).

The WHO (1998) review of boron noted that highly water-soluble materials are unlikely to bioaccumulate to any significant degree and that borate species are all present essentially as undissociated and highly soluble boric acid at neutral pH. The available data indicate that both experimental data and field observations support the interpretation that borates are not significantly bioaccumulated (ECHA).

Bioconcentration factors of < 0.1 to 10.5 L/kg have been reported from laboratory tests of fish and oysters (Thompson et al. 1976). Saiki et al. (1993) measured boron levels in aquatic food chains and observed the highest concentrations of boron in detritus and filamentous algae. Invertebrates and fish had lower concentrations, indicating that bioaccumulation was not occurring. Based on these data, boron does not bioaccumulate in the aquatic environment (ECHA).

IV. HUMAN HEALTH HAZARD ASSESSMENT

No information is available.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No values were derived.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Ulexite does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

There are no mammalian or aquatic toxicity studies on ulexite. Toxicity for boron is provided within this section.

Boron is of a low toxicity concern to aquatic organisms. Although boron is required by plants at low concentrations, at high concentrations it is toxic. In Australia, it is generally accepted that boron toxicity will pose a risk to terrestrial plants when soil concentrations exceed 15 mg/kg of extractable boron. The phytotoxicity of boron is dependent on the plant species and soil type (DoEE, 2017).

B. Aquatic Toxicity

Acute Studies

Table 2 lists the results of acute aquatic toxicity studies on boron.

Table 2: Acute Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
P. promelas	4-day LC_{50}	79.7 mg/B/L	2	ECHA
Freshwater invertebrates	48-hr LC_{50}	64 to >544 mg/B/L	2	ECHA
Pseudokirchneriella subcapitata	72-hr EC_{50}	52.4 mg/B/L	2	ECHA

1 – CAS No. 7440-42-8

Chronic Studies

Table 3 lists the results of chronic aquatic toxicity studies on boron.

Table 3: Chronic Aquatic Toxicity Studies on Boron[1]

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Micropterus salmoides	4d-EC_{10}	36.8 mg/B/L	2	ECHA
Oncorhynchus mykiss	long term NOEC-LOEC	19.2. mg/B/L	2	ECHA
Brachydanio rerio	long term NOEC-LOEC	36.mg/B/L	2	ECHA
Pimephales promelas	long term NOEC-LOEC	21.3 mg/B/L	2	ECHA
Daphnia magna	NOEC	13.9 mg/B/L	2	ECHA
Hyalella Azteca	NOEC	6.3 mg/B/L	2	ECHA
Chironomus riparius	NOEC	20.1 mg/B/L	2	ECHA
Brachionus calyciflorus	NOEC	24.6 mg/B/L	2	ECHA
Lampsilis siliquoidea	NOEC	30 mg/B/L	2	ECHA

1 – CAS No. 7440-42- 8 for boron

ANZG has developed a water quality guideline for boron (ANZG, 2021). Very high reliability default guideline values (DGVs) for (dissolved) boron in freshwater were derived from 22 chronic (long-term) toxicity data, comprising eight fish, two amphibians, three crustaceans,

one bivalve, three macrophytes, one green microalga, three diatoms and one blue–green alga. The DGVs for 99, 95, 90 and 80% species protection are 340 µg/L, 940 µg/L, 1,500 µg/L and 2,500 µg/L, respectively. The 95% species protection level for boron in freshwater (940 µg/L) is recommended for adoption in the assessment of slightly-to-moderately disturbed ecosystems.

C. Terrestrial Toxicity

Relevant and reliable chronic no-effects values were identified for 39 terrestrial species or microbial processes. No-effect levels for dissolved boron ranged between 7.2 mg B/kg soil dw and 86.7 mg B/kg soil dw. The plant *Zea mays* was the most sensitive trophic level. The least sensitive species was the nematode *C.elegans*. A Species Sensitivity Distribution (SSD) has been developed for the assessment of boron in the terrestrial compartment, using the reliable species-specific chronic toxicity effect levels that have been generated in various research studies (ECHA) [KI Score = 2].

D. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Ulexite is a naturally-occurring mineral. For the purposes of this PBT assessment, the persistence criteria is not considered applicable to this inorganic substance.

Bioaccumulation is not applicable to naturally-occurring minerals, such as ulexite. Although boron is slowly released from ulexite, limited data indicate that bioaccumulation is not significant in aquatic and terrestrial food chains. Thus, it does not meet the criteria for bioaccumulation.

There are no aquatic toxicity studies on ulexite. The lowest chronic toxicity value for boron is > 0.1 mg/L. The acute E(L)C_{50} values for boron is > 1 mg/L. Thus, based on boron, ulexite does not meet the criteria for toxicity.

Therefore, ulexite is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

GHS07, GHS08

B. Labelling

Warning!

Danger!

According to the classification provided by companies to ECHA in CLP notifications this substance may damage fertility or the unborn child and causes serious eye irritation.

C. Pictogram



X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water spray, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Ulexite is non-flammable, combustible, or explosive. It is a flame retardant.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and protective clothing.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment.

Environmental Precautions

Ulexite is slightly water-soluble; at high concentrations it may cause damage to trees or vegetation by root absorption. Do not flush to drains.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage And Handling

General Handling

No special measures necessary provided product is used correctly.

Other Handling Precautions

Avoid eye and skin contact. Avoid creating or inhaling dust.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for ulexite.

Engineering Controls

None

Personal Protection Equipment

Respiratory Protection: Respiratory protection is not required.

Hand Protection: Chemical resistant protective gloves.

Skin Protection: Body protection must be chosen depending on activity and possible exposure.

Eye protection: Safety glasses with side-shields.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Ulexite is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

American Borate Company. (2016). Technical specifications on Ulexite 45 micron ground. Available at: http://www.americanborate.com/media/19191/ulexite-1319-33-1-2016-technical-specification.pdf.

ANZG. (2021). Toxicant default guideline values for aquatic ecosystem protection: Boron in freshwater. Australian and New Zealand Guidelines for Fresh and Marine Water Quality. CC BY 4.0. Australian and New Zealand Governments and Australian state and territory governments, Canberra, ACT, Australia.

Broschat, T.K. (2008). Release rates of soluble and controlled-release boron fertilizers. HorTechnology 18(3): 471-474.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

DoEE. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

Etimine USA, Inc. (2016). Safety Data Sheet on Ulexite. Available at: http://www.etimineusa.com/sites/etimineusa.com/files/SDS%20-%20Ulexite%202016%20-%202018_0.pdf

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Saiki, M.J., Jennings, M.R., and Brumbaugh, W.B. (1993). Boron, Molybdenum, and Selenium in aquatic food chains from the Lower San Joaquin River and its tributaries, California. Archives of Environmental Contamination and Toxiciology. 24, 307-319.

Thompson et al. (1976). Toxicity, uptake and survey studies of boron in the marine environment. Water Research Vol. 10. pp 869 to 875, 1976.

WHO. (1998). World Health Organisation, Environmental health criteria 204 – boron, viewed 26 August 2015. http://www.inchem.org/documents/ehc/ehc/ehc204.htm.

UREA

This dossier on urea (CAS RN 57-13-6) presents the most critical studies pertinent to the risk assessment of the substance in its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. SUBSTANCE IDENTIFICATION

Chemical Name (IUPAC): Urea

CAS RN: 57-13-6

Molecular formula: CH_4N_2O

Molecular weight: 60.056 g/mol

Synonyms: carbamide; carbonyldiamide; isourea

SMILES: C(=O)(N)N

II. PHYSICAL AND CHEMICAL PROPERTIES

Table 1: Overview of the Physico-chemical Properties of Urea

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	2	ECHA
Melting Point	133.3°C	1	ECHA
Boiling Point	Urea decomposes before the boiling point is reached	2	ECHA
Density	1330 kg/m^3 @ 20°C	1	ECHA
Vapour Pressure	0.00016 Pa @ 25°C	2	ECHA
Partition Coefficient (log K_{ow})	-1.73 at 22°C	1	ECHA
Water Solubility	624 g/L at 20°C	1	ECHA
Flash Point	Not applicable as substance is solid	1	ECHA
Auto flammability	There was no self-ignition observed up to the melting point	2	ECHA
Viscosity	Not applicable as substance is solid	1	ECHA

III. ENVIRONMENTAL FATE PROPERTIES

A. Summary

Urea is hydrophilic and readily biodegradable due to enzymatic mineralisation. This substance is not expected to sorb to soils or sediments based on its low log K_{ow} value. In addition to this, urea is not expected to bioaccumulate.

B. Biodegradation

Urea is considered to be readily biodegradable. In an OECD Guideline 302B (Inherent biodegradability) study, degradation levels of 3% (3 hours), 52% (7 hours), 60% (10 days), 85% (14 days) and 96% (16 days) was seen. Urea is ultimately biodegradable according to this study. (ECHA) [KI Score = 2].

In an OECD Guideline 301 A (Ready Biodegradability DOC Die Away Test) study using read-across substance 1,3 dimethylurea, the biodegradation of urea was found to be 90-100% after 21 days (ECHA) [KI score = 1].

In a non-guideline study in soil, the main mode of degradation of urea was found to be enzymatic mineralisation to ammonia and bicarbonate (ECHA) [KI Score = 2].

In an OECD Guideline 304 A (Inherent Biodegradability in Soil) study, 64% degradation was observed in soil after 30 hours of incubation. (ECHA) [KI score = 2].

C. Environmental Distribution

A 30-day study found that the K_{oc} value for urea is 0.037 to 0.064 L/kg which indicates that it is unlikely to partition to organic matter in in soil (ECHA) [KI Score = 2]. If released to water, based on this K_{oc} value and high water solubility, urea is not expected to adsorb to suspended solids or sediments. Similarly, if released to soil, urea is expected to have very high mobility.

D. Bioaccumulation

Urea is not expected to bioaccumulate based on its low K_{ow} value. Additionally, urea is utilised by fish species as a nutrient and is excreted by some species as a product of protein catabolism (ECHA).

In a 6 to 72 hr bioaccumulation study using carp (*Cyprinus carpio*), the concentration of urea was found to be equally distributed between tissue and water during all time periods; thus, the bioconcentration factor (BCF) would be 1 for this species. In 3-day static-system tests using golden ide fish (*Leuciscus idus melanotus*), the BCF of urea was <10. According to a classification scheme, these BCF values suggest the potential for bioconcentration in aquatic organisms is low (PubChem).

IV. HUMAN HEALTH HAZARD ASSESSMENT

A. Summary

Urea is of very low acute oral toxicity in the rat and mouse. Urea is a mild eye irritant. It is not a skin irritant and is very unlikely to be a skin sensitiser. No systemic toxicity was seen in

rats and mice exposed to urea in the diet. Urea is not genotoxic and is not carcinogenic. Developmental toxicity testing in rats dosed orally up to 1000 mg/kg bw/day did not result in adverse effects. There are no studies in animals showing clear evidence of reproductive effects.

B. Acute Toxicity

Oral

In an OECD Guideline 401 (Acute Oral Toxicity) study, urea was found to be of low acute oral toxicity. The LD_{50} of urea in Wistar rats was determined to be 14,300 and 1,500 mg/kg bw/day in male and females, respectively (ECHA) [KI score = 2].

In another study, mice were exposed to urea via oral gavage. The LD_{50} was determined to be 11,500 mg/kg bw/day and 13,000 mg/kg bw/day in male and female mice respectively (ECHA) [KI score = 2].

Inhalation

No data are available from acute inhalation toxicity. The substance is a non-volatile solid and is produced as crystals with a particle size of >100 um. There is therefore no potential for inhalation exposure. In addition, the substance has been demonstrated to be of very low toxicity by other routes of exposure (ECHA).

Dermal

No data were available.

C. Irritation

Skin

An OECD Guideline 404 (Acute Dermal Irritation / Corrosion) was conducted to determine the skin irritation potential of urea to New Zealand White rabbits. The rabbits were exposed to urea for 4 hours and were observed 72 hours after dressing removal. Urea was found to be non-irritating to the skin of rabbits (ECHA) [KI score = 1].

Eye

An OECD Guideline 405 (Acute Eye Irritation / Corrosion) primary eye irritation study was performed using Vienna White rabbits exposed to urea. Urea was determined to be mildly irritating to the eyes of Vienna White rabbits (ECHA) [KI Score = 2].

D. Sensitisation

No data were available. Urea is naturally present at relatively high concentrations in human skin (up to 1% by weight) and it is widely used in skin creams to treat dry and irritant skin conditions (ECHA). This substance is not considered to be a skin sensitiser.

E. Repeated Dose Toxicity

Oral

In an NCI screening study, C57BL mice and Fischer 344 rats were exposed to urea via their feed for 12 months followed by a 4-month recovery period. No evidence of toxicity was seen in this study at dose levels of up to 45000 ppm. Survival and bodyweights were unaffected by treatment. Gross and microscopic pathology did not reveal any treatment-related effects. It was concluded that urea is of very low chronic toxicity. Using default conversion factors, the dose level of 45000 ppm is calculated to be equivalent to approximately 2250 mg/kg bw/day in the rat and 6750 mg/kg bw/day in the mouse (ECHA) [KI score = 2].

Inhalation

No data were available.

Dermal

In a subacute (28-day) toxicity study Wistar rats were exposed to urea on their back skin (20 cm^2 in size). There was no dose dependent toxicity observed in this study. Bodyweights, food and water consumption were unaffected by treatment. Clinical chemistry, haematology and urinalysis parameters were comparable in all groups. There was no effect of treatment on organ weights or pathology (ECHA) [KI score = 2].

F. Genotoxicity

In Vitro Studies

The results of the *in vitro* genotoxicity studies on urea based are presented in Table 2.

Table 2: *In Vitro* Genotoxicity Studies on Urea

Test System[1]	Results*		Klimisch Score	Reference
	-S9	+S9		
OECD Guideline 471 (Bacterial Reverse Mutation Assay) S. typhimurium, other: TA98, TA100, TA1537	-	-	2	ECHA
OECD Guideline 471 (Bacterial Reverse Mutation Assay) S. typhimurium TA 1538 and S9 - liver of male Sprague-Dawley rats	-	-	2	ECHA
Alkaline elution/rat hepatocyte assay	-	-	2	ECHA
Rapid genotoxicity test measuring proportion of single to double stranded DNA breaks by alkaline unwinding and hydroxyapatite elution in mouse lymphoma cells	-	-	2	ECHA

*+, positive; -, negative.

In Vivo Studies

A positive result is reported in a mouse bone marrow assay of unconventional design, however this study is not considered to be reliable (ECHA).

G. Carcinogenicity

Oral

A 12-month carcinogenesis screening study was performed using Fischer 344 rats and C57BL mice were exposed to urea in the diet at concentrations of 4500, 9000 or 45000 ppm for 12 months. Five animals/sex/group were sacrificed at the end of the 365-day exposure period and a comprehensive list of tissues were investigated histopathologically; interim deaths were similarly investigated. All remaining animals were sacrified after the 4-month recovery period and investigated histopathologically. There were no signs of toxicity. A significant linear trend in the incidence of interstitial cell tumours was noted in male rats. The incidence was 21/50 in controls 27/48, 25/48 and 35/50 in the low, intermediate and high dose groups respectively. The authors did not consider this finding to be of biological significance as the background incidence of this tumour type is noted to be up to 100% in F344 rats. A significantly increased incidence of haematopoietic tumours (malignant lymphoma) was seen in female mice in the mid-dose group. The incidence of this finding was 10 -92 in controls; 7/43, 10/38 and 9/50 in low, mid and high dose group animals, respectively. There was no relationship to treatment in the absence of a dose-response relationship. The NOAEL was determined to be 45,000 ppm (4.5% in the diet). Using default conversion factors, the dose level of 45000 ppm is calculated to be equivalent to approximately 2250 mg/kg bw/day in the rat and 6750 mg/kg bw/day in the mouse (ECHA) [KI score = 2].

Inhalation

No studies are available.

Dermal

No studies are available.

H. Reproductive Toxicity

No studies are available. Large quantities of urea are formed naturally in the human body as a consequence of normal protein catabolism. Urea is shown to be essentially without toxicity in the available studies and no effects (organ weight, gross pathology, histopathology) were observed on the reproductive organs of rats and mice exposed to urea at very high dietary levels for 12 months (ECHA). The level of any primary, occupational or secondary exposure to urea is likely to be insignificant compared to the quantities (20-50 g/day) produced by normal metabolism and present at high concentrations in the blood. It is therefore considered that urea is very unlikely to be a reproductive toxin (ECHA).

I. Developmental Toxicity

An OECD Guideline 414 study (Prenatal Developmental Toxicity Study) was performed on CD rats exposed to urea via oral gavage for 22 days. The rats were dosed daily via oral gavage at dose levels of 100, 300, or 1,000 mg/kg-bw/day from the 6th to the 20th day of pregnancy. In the dams, there were no item-related effects on the maternal and reproductive parameters.

In the fetuses, there was also no test item-related influence on the prenatal fetal development and no malformations nor variations were noted during the macroscopic, skeletal and soft tissue examinations. In conclusion, the NOAEL was above 1000 mg Urea/kg bw/day for maternal developmental and foetal toxicity as well as for teratogenicity. It is considered extremely unlikely that occupational, primary or secondary exposure to urea will result in developmental toxicity as the levels of exposure will be insignificant compared to those present in the maternal and foetal circulation as a result of protein catabolism (ECHA) [Kl Score = 1].

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

The toxicological reference values developed for urea follow the methodology discussed in enHealth (2012). The approach used to develop drinking water guidance values is described in the Australian Drinking Water Guidelines (ADWG, 2021).

A. Non-Cancer

Oral

Developmental toxicity testing in rats dosed orally up to 1000 mg/kg bw/day did not result in adverse effects. This NOAEL will be used for determining the oral reference dose (RfD) and the drinking water guidance value.

Oral Reference Dose (oral RfD)

Oral RfD = NOAEL / (UF_A x UF_H x UF_L x UF_{Sub} x UF_D)

Where:

UF_A (interspecies variability) = 10
UF_H (intraspecies variability) = 10
UF_L (LOAEL to NOAEL) = 1
UF_{Sub} (subchronic to chronic) = 10
UF_D (database uncertainty) = 1
Oral RfD = 1000/(10 x 10 x 1 x 1 x 10 x 1) = 1000/1000 = 1 mg/kg/day.

Drinking water guidance value

Drinking water guidance value = (animal dose) x (human weight) x (proportion of intake from water) / (volume of water consumed) x (safety factor)

Using the oral RfD,

Drinking water guidance value = (oral RfD) x (human weight) x (proportion of water consumed) / (volume of water consumed)

Where:

Human weight = 70 kg (ADWG, 2021)
Proportion of water consumed = 10% (ADWG, 2021)
Volume of water consumed = 2L (ADWG, 2021)
Drinking water guidance value = (1 x 70 x 0.1)/2 = 3.5 mg/L

B. Cancer

Urea is not considered a carcinogen. Thus, a cancer reference value will not be calculated for this substance.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Urea does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Summary

Urea is of very low acute toxicity to aquatic organisms.

B. Aquatic Toxicity

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on urea.

Table 3: Acute Aquatic Toxicity Studies on Urea

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Golden orfe fish	48-hour LC_{50}	10,000	2	ECHA
Tilapia mossambica	96-hour EC_{50}	>20,000	2	ECHA
Barilius barna	96-hour EC_{50}	>9100	2	ECHA
Daphnia magna	24-hour EC_{50}	>10 000	2	ECHA
Helisoma trivolvis	48-hour LC_{50}	13,477	2	ECHA
Biomphalaria havanensis	48-hour LC_{50}	21,412	2	ECHA

Chronic Studies

No chronic aquatic toxicity studies are available for fish or invertebrates. Urea is of low toxicity to fish since it is a normal product of protein catabolism and fish have evolved effective excretion mechanisms. In addition to this, microorganisms incorporate urea in the nitrogen cycle (ECHA).

The 192-hour and 7-day study of the toxicity threshold for *Scenedesmus quadricauda* (green algae) is > 10,000 mg/L (ECHA) [KI score = 2]. The 192-hour toxicity threshold for *Microcystis aeruginosa* (blue-green algae) is 47 mg/L (ECHA) [KI score = 2].

C. Terrestrial Toxicity

No toxicity data are available.

D. Calculation of PNEC

The PNEC calculations for urea follow the methodology discussed in DEWHA (2009).

PNEC water

Experimental results are available for three trophic levels. Acute E(L)C_{50} values are available for fish (9,100 mg/L) and invertebrates (>10,000 mg/L). Toxicity threshold values from long-term studies are available for algae (47 mg/L). On the basis that the data consists of short-term results from two trophic levels and long-term results from one trophic levels, an assessment factor of 50 has been applied to the chronic threshold value of 47 mg/L for algae (most sensitive species). Therefore, the $PNEC_{water}$ is 0.94 mg/L.

PNEC sediment

Urea is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and log K_{oc} values, the substance is not expected to bind substantially to sediment. Therefore, a PNEC for sediment has not been calculated.

PNEC soil

Urea is expected to degrade rapidly in the environment. Moreover, based on the low K_{ow} and K_{oc} values, the substance is not expected to bind substantially to soil. Therefore, a PNEC for soil has not been calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Urea is readily biodegradable in the environment based on its low log K_{ow} and K_{oc} values. Thus, it does not meet the screening criteria for persistence.

The estimated log K_{ow} is equal to -1.73. Measured bioconcentration factors are less than 10. Based on these values, urea has a low potential for bioaccumulation. Therefore, urea does not meet the screening criterion for bioaccumulation.

The toxicity threshold values from chronic aquatic toxicity studies are > 0.1 mg/L. The acute E(L)C_{50} values for fish and invertebrates are > 1 mg/L. Thus, urea does not meet the criteria for toxicity.

The overall conclusion is that urea is not a PBT substance.

IX. CLASSIFICATION AND LABELLING

A. Classification

Not classified.

B. Signal word

None

C. Pictogram

None

X. SAFETY AND HANDLING

Please refer to the product SDS for additional information and confirmation of the information provided herein.

A. First Aid

Eye Contact

Immediately flush open eyes with plenty of water for at least 15 minutes. Remove contacts, if present and easy to do. Get medical attention immediately, preferably a physician for an ophthalmologic examination.

Skin Contact

For minor skin contact, avoid spreading material on unaffected skin. Remove and isolate contaminated clothing. Wash the contaminated area of body with soap and fresh water. Get medical attention. Launder contaminated clothing before reuse.

Inhalation

Move person to fresh air. Administer oxygen if breathing is difficult. Do not use mouth-to-mouth method if victim inhaled the substance; give artificial respiration with the air of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Give artificial respiration if victim is not breathing. Get medical attention immediately.

Ingestion

Do not induce vomiting. Get medical attention immediately.

Notes to Physician

All treatments should be based on observed signs and symptoms of distress in the patient.

B. Fire Fighting Information

Extinguishing Media

Use water spray or fog, foam, dry chemical or carbon dioxide.

Specific Exposure Hazards

Emits toxic fumes under fire conditions. Depending on conditions, decomposition products may include the following: ammonia, carbon dioxide, carbon monoxide.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus and chemical-protective clothing.

C. Accidental Release Measures

Personal Precautions

Isolate area. Keep unnecessary and unprotected personnel from entering the area. Use personal protective clothing. Ensure adequate ventilation. Wear respiratory protection if ventilation is inadequate. Do not breath mist, vapours or spray. Avoid contact with skin, eyes and clothing. Eliminate all sources of ignition.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Eliminate all sources of ignition. Pick up with suitable absorbent material and transfer to a container for chemical waste. For large amounts: dike spillage and pump off product into container for chemical waste. Dispose of contaminated material as prescribed.

D. Storage And Handling

General Handling

Keep away from heat, sparks and flame. Avoid contact with eyes, skin and clothing. Avoid breathing vapour. Wash thoroughly after handling. Keep container closed. Use with adequate ventilation.

Storage

Keep container tightly closed. Store away from heat and light.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure standard for urea.

Engineering Controls

Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protection Equipment

Respiratory Protection: If workers are exposed to concentrations above the exposure limit, they must use appropriate, certified respirators. If there are no applicable exposure limit requirements or guidelines, use an approved respirator. Selection of air-purifying or positive pressure supplied-air will depend on the specific operation and the potential airborne concentration of the product. For emergency conditions, use an approved positive-pressure

self-contained breathing apparatus. The following should be effective types of air-purifying respirators: organic vapour cartridge with a particulate pre-filter.

Hand Protection: Use gloves chemically resistant to this material. Consult the SDS for appropriate glove barrier materials.

Skin Protection: Use protective clothing chemically resistant to the material. Selection of specific items such as face shield, boots, apron or full body suit will depend on the task.

Eye Protection: Use chemical goggles.

Other Precautions: Wash hands, forearms and face thoroughly after handling chemical products; before eating, smoking, and using the lavatory; and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

F. Transport Information

UN number: none

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations.

XII. REGULATORY STATUS

Australian AICS Inventory: Listed.

XIII. REFERENCES

ADWG. (2021). National Water Quality Management Strategy. Australian Drinking Water Guidelines, Section 6, Australian Government, National Health and Medical Research Council, Natural Resource Management Ministerial Council.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

ECETOC. (2000). European Centre for Ecotoxicology and Toxicology of Chemicals The Role of Bioaccumulation in Environmental Risk Assessment: The Aquatic Environment and the Related Food Web. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Technical Report No. 68, Brussels.

ECHA. ECHA REACH database: http://echa.europa.eu/information-on-chemicals/registered-substances

enHealth Human Risk Assessment [HHRA]. (2012). Environmental Health Risk Assessment, Guidelines for Assessing Human Health Risks from Environmental Hazards. Office of Health Protection of the Australian Government Department of Health.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

PubChem. National Institutes of Health. National Library of Medicine National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/

VINYLIDENE CHLORIDE/METHYLACRYLATE COPOLYMER

This dossier on vinylidene chloride/methylacrylate copolymer presents the most critical studies pertinent to the risk assessment of vinylidene chloride/methylacrylate copolymer in its use in coal seam gas extraction activities. It does not represent an exhaustive or critical review of all available data. Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

I. CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): 1,1-dichloroethene; methyl prop-2-enoate

CAS RN: 25038-72-6

Molecular formula: $(C_2H_2Cl_2)_x(C_4H_6O_2)_y$ [This substance is a polymer.]

Molecular weight: 183.03 g/mol (monomer); polymer assumed to be > 1,000 g/mol (NICNAS, 2017)

Synonyms: vinylidene chloride/methylacrylate copolymer; methyl acrylate-vinylidene chloride copolymer; 2-propenoic acid, methyl ester, polymer with 1,1-dichloroethene

SMILES: COC(=O)C=C.C=C(Cl)Cl

II. PHYSICO AND CHEMICAL PROPERTIES

No chemical-specific information is available. Vinylidene chloride/methylacrylate copolymer is a non-ionic synthetic polymer. It is formed by addition polymerisation, which typically affords high molecular weight polymers with stable saturated carbon-chain backbones. Water solubility is expected to be low based on the predominantly hydrophobic structure of the substance.

As noted, no information is available regarding the molecular weight and the percentage of low molecular weight (LMW) species in this polymer. However, synthetic addition polymers of this type are generally high to very high molecular weight species. It is assumed for this polymer that the number average molecular weight (NAMW) is greater than 1,000 daltons (Da) with an insignificant percentage of LMW species (DoEE, 2017).

III. ENVIRONMENTAL FATE PROPERTIES

No experimental data are available for vinylidene chloride/methylacrylate copolymer.

Polymers with a molecular weight greater than 1,000 g/mol generally have a negligible vapour pressure, which indicates that the chemical is likely to exist solely as particulate matter in the atmosphere. As particulate matter, atmospheric oxidation is not expected to be a significant route of environmental removal. Likewise, volatilisation from water or moist soil is not expected to occur at an appreciable rate (USEPA, 2013).

Non-ionic polymers such as vinylidene chloride/methylacrylate copolymer are not expected to be highly soluble in water based on its predominantly hydrophobic structure. If

discharged to the aquatic environment, this polymer is expected to partition to soil or sediment. It is not expected to be highly mobile if released to the soil compartment (Boethling and Nabholz, 1997).

Synthetic non-ionic polymers are not expected to undergo rapid degradation (NICNAS, 2017). However, the high molecular weight of the polymer is expected to preclude or minimise bioaccumulation. Polymers with a number average molecular weight (NAMW) greater than 1,000 g/mol cannot cross biological membranes (Boethling and Nabholz, 1997).

IV. HUMAN HEALTH HAZARD ASSESSMENT

These polymers are considered chemically and biologically inert. As such, no toxicity studies have been conducted on this material.

NICNAS has assessed vinylidene chloride/methylacrylate copolymer in an IMAP Tier 1 assessment and considers it a polymer of low concern[1]. In addition, based on an assessment of human health and environmental hazards, NICNAS also identified vinylidene chloride/methylacrylate copolymer as a chemical of low concern to the environment (NICNAS, 2017 and DoEE, 2017). Chemicals of low concern are unlikely to have adverse environmental effects or be a concern to human health if they are released to the environment from coal seam gas operations.

V. DERIVATION OF TOXICOLOGICAL REFERENCE AND DRINKING WATER GUIDANCE VALUES

No toxicological reference values or drinking water guidance values were developed.

VI. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICO-CHEMICAL PROPERTIES

Vinylidene chloride/methylacrylate copolymer does not exhibit the following physico-chemical properties:

- Explosivity
- Flammability
- Oxidising potential

VII. ENVIRONMENTAL HAZARD ASSESSMENT

A. Aquatic Toxicity

No ecotoxicity data was identified for vinylidene chloride/methylacrylate copolymer. Information on Non-Ionic Polymers Group (DoEE, 2017) is provided below.

> *"Non-ionic polymers with low water solubility, such as the methyl acrylate-vinylidene chloride copolymer, generally have low toxicity to aquatic life (Beothling and Nabholz 1997). Insoluble non-ionic polymers have low bioavailability and their adverse effects result from physical. effects such as*

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=25038-72-6

occlusion of respiratory organs (e.g. the gills of fish). These adverse effects occur only at very high loading levels in water (Beothling and Nabholz 1997).

Water soluble or dispersible non-ionic polymers, such as polyacrylamide, are also typically of low concern for ecotoxicity. Non-ionic polymers with NAMW greater than 1 000 cannot be absorbed across biological membranes in aquatic organisms, and therefore toxicity only occurs through indirect effects such as chelation of essential nutrients (Beothling and Nabholz 1997). However, the structure of polyacrylamide suggests that it will have low potential to act by this mode of action. This is further supported by median effective concentration (EC50) and median lethal concentration (LC50) values available for other water soluble or dispersible non-ionic polymers, which are greater than 100 mg/L (Beothling and Nabholz 1997).

Water soluble or dispersible polymers with NAMW less than 1 000 Da, or significant levels of LMW substances and trapped monomers, are of potential concern because of their increased bioavailability. However, this assessment was conducted assuming that the polymers in this group have NAMW greater than 1 000 Da and the percentage of LMW species is low."

B. Terrestrial Toxicity

No data are available.

C. Calculation of PNEC

No PNEC values were calculated.

VIII. PERSISTENCE, BIOACCUMULATION AND TOXICITY (PBT) ASSESSMENT

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Vinylidene chloride/methylacrylate copolymer is not expected to be biodegradable. Thus, it meets the criteria for persistence.

Vinylidene chloride/methylacrylate copolymer is not expected to bioaccumulate. Polymers with a NAMW greater than 1,000 g/mol cannot cross biological membranes (Boethling and Nabholz, 1997). Thus, it does not meet the screening criteria for bioaccumulation.

No aquatic toxicity studies are available for vinylidene chloride/methylacrylate copolymer. It is expected to be a low concern of toxicity to aquatic organisms because of its low potential for bioavailability. Thus, it does not meet the screening criteria for toxicity.

The overall conclusion is that vinylidene chloride/methylacrylate copolymer is not a PBT substance.

IX. CLASSIFICATION AND LABELING

A. Classification

Not classified.

B. Labelling

No signal word.

C. Pictograms

None

X. SAFETY AND HANDLING

A. First Aid

Eye Contact

In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. If symptoms persist, seek medical advice.

Skin Contact

Wash thoroughly with soap and water.

Inhalation

If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion

Rinse mouth with water and then drink plenty of water. Never give anything by mouth to an unconscious person. If symptoms develop, seek medical advice.

B. Fire Fighting Information

Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Specific Exposure Hazards

Burning produces harmful and toxic fumes. Heat from fire may melt, decompose polymer and generate flammable vapours. Combustion products may include: carbon oxides, hydrogen chlorine gas.

Special Protective Equipment for Firefighters

Wear self-contained breathing apparatus.

C. Accidental Release Measures

Personal Precautions

Use appropriate protective equipment. Potential combustible dust hazard. Avoid generating dust. Creates dangerous slipping hazard on any hard smooth surface.

Environmental Precautions

Prevent from entering sewers, waterways or low areas.

Steps to be Taken if Material is Released or Spilled

Scoop up and remove.

D. Storage and Handling

General Handling

Avoid dust accumulation in enclosed space. Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Electrostatic charge may build up during handling. Equipment, container and metal containers should be grounded and bonded.

Storage

Keep container tightly closed and in a dry and well-ventilated place. Keep in a cool place. Use adequate ventilation to avoid excessive dust accumulation. Store away from excessive heat and away from strong oxidising agents. Take measures to prevent the build-up of electrostatic charge.

E. Exposure Controls / Personal Protection

Occupational Exposure Standards

Workplace Australia has not established an occupational exposure limit for vinylidene chloride/methylacrylate copolymer.

Engineering Controls

Use in a well-ventilated area. Avoid creating dust. Take precautionary measures against static charge.

Personal Protection Equipment

Respiratory Protection: Not normally needed; however, if significant exposures are possible, then the following respirator is recommended: Dust/mist respirator.

Hand Protection: Normal work gloves.

Skin Protection: Normal work coveralls.

Eye Protection: Wear safety glasses or goggles to protect against exposure.

Other Precautions: Handle in accordance with good industrial hygiene and safety practice. Eyewash fountains and safety showers must be easily accessible.

F. Transport Information

Vinylidene chloride/methylacrylate copolymer is not considered hazardous for purposes of transportation by road or rail. An Australian Dangerous Goods code is not required.

XI. DISPOSAL MANAGEMENT

Disposal should be in accordance with all local, state and federal regulations

XII. REGULATORY INFORMATION

Australian AICS Inventory: Listed.

XIII. REFERENCES

Boethling, R.S. and Nabholz, J.V. (1997). 'Environmental assessment of polymers under the US Toxic Substances Control Act', in Hamilton J and Sutcliffe R (eds), Ecological assessment of polymers: strategies for product stewardship and regulatory programs, Van Nostrand Reinhold, New York, USA, pp 187-234.

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Environmental risks associated with surface handling of chemicals used in coal seam gas extraction in Australia, Project report Appendices A, B, C, D, F, and G prepared by the Chemicals and Biotechnology Assessments Section (CBAS) in the Department of the Environment and Energy as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

NICNAS (2017), Chemicals of low concern for human health based on an initial assessment of hazards, Project report prepared by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) as part of the National Assessment of Chemicals Associated with Coal Seam Gas Extraction in Australia, Commonwealth of Australia, Canberra.

United States Environmental Protection Agency (USEPA). (2013). Interpretive Assistance Document for Assessment of Polymers: Sustainable Futures Summary Assessment. June 2013.

Appendix D Safety Data Sheets

Appendix D.1 March 2020 Safety Data Sheets

Standard Hydraulic Fracturing System SDS

HALLIBURTON

SAFETY DATA SHEET

ACETIC ACID 60%

Revision Date: 19-Mar-2015 **Revision Number:** 9

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name ACETIC ACID 60%

Other means of Identification

Synonyms: None

Product Code: HM004481

Recommended use of the chemical and restrictions on use

Recommended Use Solvent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion / irritation	Category 1 - H314
Serious Eye Damage / Eye Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word Danger

Hazard Statements
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation
H226 - Flammable liquid and vapor

Precautionary Statements

Prevention
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/Bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301+ P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Acetic acid	64-19-7

Other hazards which do not result in classification
None known

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification C - Corrosive.

Risk Phrases
R10 Flammable.
R34 Causes burns.
R37 Irritating to respiratory system.

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Acetic acid	64-19-7	60 - 100%	Skin Corr. 1A (H314) Eye Corr. 1 (H318) STOT SE 3 (H335) Flam. Liq. 3 (H226)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Use water spray to cool fire exposed surfaces. Decomposition in fire may produce harmful gases. Do not allow runoff to enter waterways.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and

remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 24 months. Store locked up.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Acetic acid	64-19-7	TWA: 10 ppm TWA: 25 mg/m^3 STEL: 15 ppm STEL: 37 mg/m^3	TWA: 10 ppm STEL: 15 ppm

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Respiratory Protection Organic vapor/acid gas respirator.

Hand Protection Impervious rubber gloves.

Skin Protection Full protective chemical resistant clothing.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid **Color:** Clear

Odor: Acrid **Odor Threshold:** No information available

Property Remarks/ - Method	Values
pH:	1.38
Freezing Point/Range	16 °C
Melting Point/Range	No data available
Boiling Point/Range	117 °C / 244 °F
Flash Point	55 °C / 131 °F PMCC
upper flammability limit	16%
lower flammability limit	5.4%
Evaporation rate	No data available
Vapor Pressure	11.7 mmHg @ 20 C
Vapor Density	No data available
Specific Gravity	1.05
Water Solubility	Soluble in water
Solubility in other solvents	No data available

Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	60.6 (g/mole)
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
Keep away from heat, sparks and flame.
10.5. Incompatible Materials
Strong alkalis.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Acetic acid	64-19-7	3310 mg/kg (Rat) 600 mg/kg (Rabbit) 4960 mg/kg (Mouse)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4h

Immediate, delayed and chronic health effects from exposure

Inhalation	Causes severe respiratory irritation.
Eye Contact	Causes eye burns.
Skin Contact	Causes skin burns which may not be immediately painful or visible.
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Acetic acid	64-19-7	Corrosive to skin

Substances	CAS Number	Eye damage/irritation
Acetic acid	64-19-7	Corrosive to eyes

Substances	CAS Number	Skin Sensitization
Acetic acid	64-19-7	Not regarded as a sensitizer.

Substances	CAS Number	Respiratory Sensitization
Acetic acid	64-19-7	No information available

Substances	CAS Number	Mutagenic Effects
Acetic acid	64-19-7	In vivo tests did not show mutagenic effects. In vitro tests did not show mutagenic effects

Substances	CAS Number	Carcinogenic Effects
Acetic acid	64-19-7	Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Acetic acid	64-19-7	Did not show teratogenic effects in animal experiments. Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Acetic acid	64-19-7	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Acetic acid	64-19-7	Not applicable due to corrosivity of the substance.

Substances	CAS Number	Aspiration hazard
Acetic acid	64-19-7	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Acetic acid	64-19-7	EC50 90 mg/L (Microcystis aeruginosa) EC50 (72h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Skeletonema costatum)	LC50 79 mg/L (Pimephales promelas) LC50 75 mg/L (Pimephales promelas) LC50 (96h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Oncorhynchus mykiss)	NOEC (16h) 1150 mg/L (Pseudomonas putida)	EC50 47 mg/L (Daphnia magna) LC50 32 mg/L (Artemia salina) EC50 (48h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Daphnia magna) NOEC (21d) 31.4 - 37.9 mg/L (Daphnia magna) (reproduction)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Acetic acid	64-19-7	Readily biodegradable (99% @ 7d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Acetic acid	64-19-7	-0.17 BCF = 3.16 (Calculated)

12.4. Mobility in soil

Substances	CAS Number	Mobility
Acetic acid	64-19-7	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number: UN2790
UN Proper Shipping Name: Acetic Acid Solution
Transport Hazard Class(es): 8
Packing Group: II
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number
S6

16. Other information

Date of preparation or review

Revision Date: 19-Mar-2015

Revision Note Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
R10 Flammable.
R34 Causes burns.
R35 Causes severe burns.
R37 Irritating to respiratory system.

Full text of H-Statements referred to under sections 2 and 3
H226 - Flammable liquid and vapor
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

BE-9

Revision Date: 13-Oct-2017 **Revision Number:** 20

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name BE-9

Other means of Identification

Synonyms None

Hazardous Material Number: HB006583

Recommended use of the chemical and restrictions on use

Recommended Use Biocide

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 1 - H400
Chronic Aquatic Toxicity	Category 2 - H411

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H400 - Very toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P391 - Collect spillage

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Tributyl tetradecyl phosphonium chloride	81741-28-8

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Tributyl tetradecyl phosphonium chloride	81741-28-8	5 - 10%	Acute Tox. 4 (H302) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases. Do not allow runoff to enter waterways. Use water spray to cool fire exposed surfaces.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Wash hands after use. Launder contaminated clothing before reuse. Do NOT consume food, drink, or tobacco in contaminated areas.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep container closed when not in use. Store away from direct sunlight. Store in a dry location. Store in a manner to prevent commingling with incompatible materials. Store away from alkalis. Store away from reducing agents. Store locked up.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Tributyl tetradecyl phosphonium chloride	81741-28-8	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Neoprene gloves. (>= 0.75 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Wear impervious protective clothing, including boots, gloves, lab coat, apron, rain jacket, pants or coverall, as appropriate, to prevent skin contact.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Clear colorless
Odor: Slight
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6-8
Freezing Point / Range	-8 - -10 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C / 212 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.95 - 1.0
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Reducing agents. Strong alkalis.

10.6. Hazardous decomposition products

Chlorine. Phosphorus acids. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Tributyl tetradecyl phosphonium chloride	81741-28-8	= 611 mg/kg (rat)	No data of sufficient quality are available	> 0.908 mg/L (rat, 4hr, mist)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue. May cause eye burns.

Skin Contact Causes severe skin irritation with tissue destruction.

Ingestion Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Lung disorders. Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Tributyl tetradecyl phosphonium chloride	81741-28-8	Causes burns (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Tributyl tetradecyl phosphonium chloride	81741-28-8	Causes severe eye irritation which may damage tissue. (Rabbit)

Substances	CAS Number	Skin Sensitization
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Respiratory Sensitization
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Mutagenic Effects
Tributyl tetradecyl phosphonium chloride	81741-28-8	No data of sufficient quality are available.

Substances	CAS Number	Carcinogenic Effects
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Reproductive toxicity
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	STOT - single exposure
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	STOT - repeated exposure
Tributyl tetradecyl phosphonium chloride	81741-28-8	No data of sufficient quality are available.

Substances	CAS Number	Aspiration hazard
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available	LC50 (96 h) 0.46 mg/L (Oncorhynchus mykiss) LC50 (96 h) 0.06 mg/L (Lepomis macrochirus)	No information available	EC50 (48 h) 0.025 mg/L (Daphnia sp.)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Tributyl tetradecyl phosphonium chloride	81741-28-8	(0% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Tributyl tetradecyl phosphonium chloride	81741-28-8	< 3

12.4. Mobility in soil

Substances	CAS Number	Mobility
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations. Incineration recommended in approved incinerator according to federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant

IMDG/IMO

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant
EMS:	EmS F-A, S-B

IATA/ICAO

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant

Special precautions during transport
None

HazChem Code
2X

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 13-Oct-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
H411 - Toxic to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

CAUSTIC SODA LIQUID

Revision Date: 16-Apr-2015 **Revision Number:** 8

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name CAUSTIC SODA LIQUID

Other means of Identification

Synonyms None

Hazardous Material Number: HM005652

Recommended use of the chemical and restrictions on use

Recommended Use pH Control

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Substances/mixtures corrosive to metal.	Category 1 - H290

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Precautionary Statements

Prevention
P234 - Keep only in original packaging.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P363 - Wash contaminated clothing before reuse
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P390 - Absorb spillage to prevent material damage
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Sodium hydroxide	1310-73-2

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Sodium hydroxide	1310-73-2	30 - 60%	Skin Corr. 1A (H314) Eye Corr. 1 (H318) STOT SE 3 (H335) Met. Corr. 1 (H290)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes	Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.
Skin	Remove contaminated clothing and launder before reuse. Destroy or properly dispose of contaminated shoes. In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

May cause eye and skin burns. May cause respiratory irritation. Causes severe skin irritation with tissue destruction. Causes severe eye irritation which may damage tissue.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May form explosive mixtures with strong acids. Reaction with steel and certain other metals generates flammable hydrogen gas.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and remove. Isolate spill and stop leak where safe.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from acids. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Sodium hydroxide	1310-73-2	2 mg/m³	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Full protective chemical resistant clothing.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Clear colorless
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	14
Freezing Point / Range	12 °C
Melting Point / Range	No data available
Boiling Point / Range	144 °C / 291 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	13 mmHg
Vapor Density	No data available
Specific Gravity	1.52
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	40
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong acids. Peroxides. Halogenated compounds. Amphoteric metals such as aluminum, magnesium, lead, tin, or zinc.
10.6. Hazardous decomposition products
None known.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
May cause eye and skin burns. May cause respiratory irritation. Causes severe skin irritation with tissue destruction. Causes severe eye irritation which may damage tissue.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hydroxide	1310-73-2	Not applicable due to corrosivity of the substance.	Not applicable due to corrosivity of the substance.	Not applicable due to corrosivity of the substance.

Immediate, delayed and chronic health effects from exposure

Inhalation	Causes severe respiratory burns.
Eye Contact	Causes severe eye burns.
Skin Contact	Causes severe burns.
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Sodium hydroxide	1310-73-2	Causes severe burns

Substances	CAS Number	Serious eye damage/irritation
Sodium hydroxide	1310-73-2	Causes severe eye burns (Rabbit)

Substances	CAS Number	Skin Sensitization
Sodium hydroxide	1310-73-2	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Sodium hydroxide	1310-73-2	No information available

Substances	CAS Number	Mutagenic Effects
Sodium hydroxide	1310-73-2	Did not show mutagenic effects in animal experiments In vitro tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Sodium hydroxide	1310-73-2	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Sodium hydroxide	1310-73-2	No information available

Substances	CAS Number	STOT - single exposure
Sodium hydroxide	1310-73-2	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Sodium hydroxide	1310-73-2	No significant toxicity observed in animal studies at concentration requiring classification. Not applicable due to corrosivity of the substance.

Substances	CAS Number	Aspiration hazard
Sodium hydroxide	1310-73-2	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Sodium hydroxide	1310-73-2	No information available	LC50(48h) 189 mg/L (Leuciscus idus melanotus) LLC50(48h) 189 mg/L (Leuciscus melanotus) LC50(24h) 145 mg/L (Poecilia reticulate) LC50(96h) 125 mg/L (Gambusia affinis) LOEL(150 d) = 25 mg/L (Lebistes reticulatus)	No information available	EC50 (48h) 40.4 mg/L (Ceriodaphnia sp.)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Sodium hydroxide	1310-73-2	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Sodium hydroxide	1310-73-2	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Sodium hydroxide	1310-73-2	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information
Australia ADG

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable
EMS:	EmS F-A, S-B

IATA/ICAO

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 16-Apr-2015

Revision Note

Full text of H-Statements referred to under sections 2 and 3
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

D-AIR 3500L

Revision Date: 05-Apr-2018 **Revision Number:** 5

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name D-AIR 3500L

Other means of Identification

Synonyms None

Hazardous Material Number: HM008316

Recommended use of the chemical and restrictions on use

Recommended Use Defoamer

Uses advised against Consumer use

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Aspiration Toxicity	Category 1 - H304

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements: H304 - May be fatal if swallowed and enters airways

Precautionary Statements

Prevention None
Response P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P331 - Do NOT induce vomiting
Storage P405 - Store locked up
Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Hydrotreated distillate	Proprietary

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrotreated distillate	Proprietary	60 - 100%	Asp. Tox. 1 (H304)

The specific chemical identity of the composition has been withheld as proprietary. The exact percentage (concentration) of the composition has been withheld as proprietary.

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin Wash with soap and water. Get medical attention if irritation persists.
Ingestion Get medical attention! If vomiting occurs, keep head lower than hips to prevent aspiration. Rinse mouth. Never give anything by mouth to an unconscious person.

Symptoms caused by exposure
Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.

Medical Attention and Special Treatment
Notes to Physician Aspiration may cause severe lung damage. Evacuate stomach in a way which avoids aspiration.

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

Do NOT spray pool fires directly with water. A solid stream of water directed into hot burning liquid can cause splattering.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use appropriate protective equipment. Do not breathe dust/fume/gas/mist/vapors/spray.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Do not breathe dust/fume/gas/mist/vapors/spray. Ensure adequate ventilation. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a well ventilated area.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrotreated distillate	Proprietary	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Ensure adequate ventilation, especially in confined areas

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational

	exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Organic vapor respirator.
Hand Protection	Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.
Skin Protection	Wear protective clothing appropriate for the work environment.
Eye Protection	Safety glasses with side-shields. If splashes are likely to occur, wear: Goggles, Face-shield.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Opaque
Odor:	Hydrocarbon	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	> 100 °C / > 212 °F PMCC
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.910 - 0.950
Water Solubility	Immiscible in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers. Strong acids. Strong alkalis.
10.6. Hazardous decomposition products
Carbon oxides.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure	Ingestion. Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrotreated distillate	Proprietary	>5000 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rabbit) (similar substance)	>5.2 mg/L (rat, 4 h, vapor) (similar substance)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact May cause mild eye irritation.

Skin Contact May cause mild skin irritation.

Ingestion Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.

Exposure Levels

No data available

Interactive effects

No data available

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrotreated distillate		Non-irritating to the skin (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Hydrotreated distillate		Non-irritating to rabbit's eye (similar substances)

Substances	CAS Number	Skin Sensitization
Hydrotreated distillate		Did not cause sensitization on laboratory animals (guinea pig) (similar substances)

Substances	CAS Number	Respiratory Sensitization
Hydrotreated distillate		Based on available data, the classification criteria are not met.

Substances	CAS Number	Mutagenic Effects
Hydrotreated distillate		In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Hydrotreated distillate		Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Hydrotreated distillate		Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)

Substances	CAS Number	STOT - single exposure
Hydrotreated distillate		No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Hydrotreated distillate		No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Hydrotreated distillate		Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing,

		wheezing, coughing up blood and pneumonia, which can be fatal.

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrotreated distillate	Proprietary	ErL50(72 h)>10000 mg/L (Skeletonema costatum)	LC50(96 h)>10000 mg/L (Scophthalmus maximus) NOELR(28 d)>1000 mg/L (fish)	No information available	LC50(48 h)>10000 mg/L (Acartia tonsa) NOELR(21 d)=1000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Hydrotreated distillate	Proprietary	Readily biodegradable (68.1% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Hydrotreated distillate	Proprietary	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Hydrotreated distillate	Proprietary	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 05-Apr-2018

Revision Note
SDS sections updated:
11

Full text of H-Statements referred to under sections 2 and 3
H304 - May be fatal if swallowed and enters airways
H336 - May cause drowsiness or dizziness

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight

CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-11001

Revision Date: 23-Jan-2017 **Revision Number:** 19

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-11001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007644

Recommended use of the chemical and restrictions on use

Recommended Use Additive

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Multi-Chem Mintech
1 Ward Road
East Rockingham
WA 6168
Australia

Telephone Number: 61 (08) 9419 5300
Fax Number: 61 (08) 9439 1055
Emergency Telephone Number: + 61 1 800 686 951

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Repeated Exposure)	Category 2 - H373
Acute Aquatic Toxicity	Category 3 - H402

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H315 - Causes skin irritation
H318 - Causes serious eye damage
H373 - May cause damage to organs through prolonged or repeated exposure
H402 - Harmful to aquatic life

Precautionary Statements

Prevention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/eye protection/face protection

Response
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P314 - Get medical attention/advice if you feel unwell

Storage None

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Diethanolamine	111-42-2

Other hazards which do not result in classification
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Diethanolamine	111-42-2	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) STOT RE 2 (H373) Aquatic Acute 2 (H401) Aquatic Chronic 3 (H412)

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, move victim to fresh air and seek medical attention.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Seek immediate medical attention/advice. Suitable emergency eye wash facility should be immediately available
Skin	Remove contaminated clothing and launder before reuse. In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. Prolonged or repeated exposure may cause damage to organs.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Carbon dioxide, dry chemical, foam.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse. Ensure adequate ventilation. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of

12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Diethanolamine	111-42-2	TWA: 3 ppm TWA: 13 mg/m^3	TWA: 1 mg/m^3

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection Wear a NIOSH certified, European Standard EN 149 (FFP2/FFP3), AS/NZS 1715, or equivalent respirator when using this product.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Rubber apron.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Water white
Odor: Characteristic
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	10.5
Freezing Point / Range	16 °C
Melting Point / Range	No data available
Boiling Point / Range	250 °C / 482 °F
Flash Point	194 °C / 382 °F PMCC
Upper flammability limit	8.5
Lower flammability limit	1.3
Evaporation rate	No data available
Vapor Pressure	0.01 mmHg
Vapor Density	No data available
Specific Gravity	1.11
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available

Autoignition Temperature	315 °C / 600 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers. Violent, explosive reaction with sulfur trioxide, decaborane, silver perchlorate, triethenyl aluminum, and hydrogen in presence of nickel catalyst at temperatures above 200 C.
10.6. Hazardous decomposition products
Oxides of nitrogen. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes skin irritation. Prolonged or repeated exposure may cause damage to organs.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethanolamine	111-42-2	620 µL/kg (Rat) 1600 mg/kg (Rat)	7640 µL/kg (Rabbit) 13,000 mg/kg (Rabbit)	3.35 mg/L (Rat)

Immediate, delayed and chronic health effects from exposure

Inhalation	May cause respiratory irritation.
Eye Contact	Causes severe eye irritation which may damage tissue.
Skin Contact	Causes skin irritation.
Ingestion	Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity Repeated overexposure may cause liver and kidney effects. Amines may form nitrosamines, a suspect carcinogen, if product is mixed with nitrates, nitrites, nitrogen oxides or other nitrosamines.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Diethanolamine	111-42-2	Causes moderate skin irritation. (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Diethanolamine	111-42-2	Causes severe eye irritation (Rabbit)

Substances	CAS Number	Skin Sensitization
Diethanolamine	111-42-2	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Diethanolamine	111-42-2	No information available

Substances	CAS Number	Mutagenic Effects
Diethanolamine	111-42-2	In vivo tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Diethanolamine	111-42-2	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Diethanolamine	111-42-2	Animal testing did not show any effects on fertility. (similar substances) Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Diethanolamine	111-42-2	No information available

Substances	CAS Number	STOT - repeated exposure
Diethanolamine	111-42-2	Causes damage to organs through prolonged or repeated exposure if swallowed: (Liver) (Blood) (Kidney)

Substances	CAS Number	Aspiration hazard
Diethanolamine	111-42-2	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Diethanolamine	111-42-2	EC50 7.8 mg/L (Desmodesmus subspicatus) EC50 (96h) 2.2 mg/L (growth rate) (Selenastrum capricornutum)	LC50 4460-4980 mg/L (Pimephales promelas) LC50 (96h) 1460 mg/L (Pimephales promelas)	EC20 >1000 mg/L (respiration rate) (activated sludge) EC90 (30min) > 1000 mg/L (Activated sludge)	EC50 (48h) 30.1 mg/L (Ceriodaphnia dubia) EC50 (48h) 55 mg/L (Daphnia magna) NOEC (21d) 0.78 mg/L (Daphnia magna) (Reproduction)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Diethanolamine	111-42-2	Readily biodegradable (88 - 97% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Diethanolamine	111-42-2	-1.71

12.4. Mobility in soil

Substances	CAS Number	Mobility
Diethanolamine	111-42-2	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 23-Jan-2017

Revision Note

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H315 - Causes skin irritation
H318 - Causes serious eye damage
H373 - May cause damage to organs through prolonged or repeated exposure if swallowed
H401 - Toxic to aquatic life
H402 - Harmful to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-13001

Revision Date: 20-Jan-2016 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-13001

Other means of Identification

Synonyms: None

Product Code: HM007646

Recommended use of the chemical and restrictions on use

Recommended Use Concentrate

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Acute Inhalation Toxicity - Dusts and Mists	Category 4 - H332
Serious Eye Damage / Eye Irritation	Category 1 - H318
Reproductive Toxicity	Category 2 - H361
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Acute Aquatic Toxicity	Category 3 - H402

Label elements, including precautionary statements

Hazard Pictograms



Signal Word Danger

Hazard Statements

H302 - Harmful if swallowed
H318 - Causes serious eye damage
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H361 - Suspected of damaging fertility or the unborn child
H402 - Harmful to aquatic life

Precautionary Statements

Prevention

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear eye protection/face protection
P281 - Use personal protective equipment as required

Response

P301+ P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Storage

P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up

Disposal

P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Sodium perborate tetrahydrate	10486-00-7

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Xn - Harmful.

Risk Phrases

R20 Harmful by inhalation.
R22 Harmful if swallowed.
R37 Irritating to respiratory system.

R41 Risk of serious damage to eyes.
R60 May impair fertility.

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Sodium perborate tetrahydrate	10486-00-7	60 - 100%	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Eye Corr. 1 (H318) Repr. 2 (H361) STOT SE 3 (H335) Aquatic Acute 3 (H402)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin Wash with soap and water. Get medical attention if irritation persists. Remove contaminated clothing and launder before reuse.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Harmful if swallowed. Harmful if inhaled. Potential reproductive hazard. May cause birth defects. May cause respiratory irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases. Releases oxygen at high temperatures.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling
Handling Precautions
Use appropriate protective equipment. Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from combustibles. Store in a cool, dry location. Store locked up.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Sodium perborate tetrahydrate	10486-00-7	Not applicable	2 mg/m^3

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Dust/mist respirator. (N95, P2/P3)
Hand Protection Impervious rubber gloves.
Skin Protection Rubber apron.
Eye Protection Dust proof goggles.
Other Precautions Eyewash fountains and safety showers must be easily accessible.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties
Physical State: Powder
Color: White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	10.2 (1%)
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	130 °C / 266 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	6.2 mmHg
Vapor Density	No data available
Specific Gravity	0.82
Water Solubility	Partly soluble
Solubility in other solvents	No data available

Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	153.86 g/mol
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Heating may cause a fire
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
Avoid contact with organic materials.
10.5. Incompatible Materials
Organic matter. All flammables, especially petroleum products, asphalt & other volatile flammables. Metal salts such as aluminum chloride. Contact with water.
10.6. Hazardous Decomposition Products
Oxygen.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Harmful if swallowed. Harmful if inhaled. Potential reproductive hazard. May cause birth defects. May cause respiratory irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium perborate tetrahydrate	10486-00-7	1800 mg/kg (Rat)	> 2000 mg/kg (Rabbit) (similar substance)	1.164 mg/L (Rat) 4h

Immediate, delayed and chronic health effects from exposure

Inhalation	Harmful if inhaled. May cause respiratory irritation. May be absorbed through inhalation contributing to symptoms listed under ingestion.
Eye Contact	Causes severe eye irritation which may damage tissue.
Skin Contact	May cause skin irritation.
Ingestion	Harmful if swallowed. Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause gastrointestinal effects and muscular dysfunction. Prolonged or repeated exposure may cause blood forming system, nervous, urinary tract and reproductive system damage.

Exposure Levels
No data available

Interactive effects

Skin disorders. None known.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Sodium perborate tetrahydrate	10486-00-7	Not irritating to skin in rabbits.

Substances	CAS Number	Eye damage/irritation
Sodium perborate tetrahydrate	10486-00-7	Causes severe eye irritation. (Rabbit)

Substances	CAS Number	Skin Sensitization
Sodium perborate tetrahydrate	10486-00-7	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)

Substances	CAS Number	Respiratory Sensitization
Sodium perborate tetrahydrate	10486-00-7	No information available

Substances	CAS Number	Mutagenic Effects
Sodium perborate tetrahydrate	10486-00-7	While some in vitro tests were positive and/or equivocal, in vivo results were negative. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Sodium perborate tetrahydrate	10486-00-7	Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Sodium perborate tetrahydrate	10486-00-7	Experiments have shown reproductive toxicity effects on laboratory animals

Substances	CAS Number	STOT - single exposure
Sodium perborate tetrahydrate	10486-00-7	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Sodium perborate tetrahydrate	10486-00-7	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Sodium perborate tetrahydrate	10486-00-7	Not applicable

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Sodium perborate tetrahydrate	10486-00-7	EC50 (96h) 19 mg/L (S. subspicatus)	LC50 (96h) 51 mg/L (Danio rerio) LOAEL (72h) 400 mg/L (Brachydanio rerio)	NOEC (3wks) 1.4 mg/L (Multi-species)	EC50 (48h) 30 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability

Sodium perborate tetrahydrate	10486-00-7	Readily biodegradable (86% @ 48h) (similar substances)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Sodium perborate tetrahydrate	10486-00-7	0.175 (similar substances) BCF 0.1 - 1.25 (similar substances)

12.4. Mobility in soil

Substances	CAS Number	Mobility
Sodium perborate tetrahydrate	10486-00-7	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 20-Jan-2016

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
R20 Harmful by inhalation.
R22 Harmful if swallowed.
R37 Irritating to respiratory system.
R41 Risk of serious damage to eyes.
R60 May impair fertility.

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H318 - Causes serious eye damage
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H361 - Suspected of damaging fertility or the unborn child
H402 - Harmful to aquatic life

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-13002

Revision Date: 21-Sep-2017 **Revision Number:** 22

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-13002

Other means of Identification

Synonyms None

Hazardous Material Number: HM007647

Recommended use of the chemical and restrictions on use

Recommended Use Breaker

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 2 - H319
Respiratory Sensitization	Category 1 - H334
Skin Sensitization	Category 1 - H317
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Oxidizing solids.	Category 3 - H272

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H272 - May intensify fire; oxidizer
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation

Precautionary Statements

Prevention
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P221 - Take any precaution to avoid mixing with combustibles
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P285 - In case of inadequate ventilation wear respiratory protection

Response
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P304 + P341 - IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Sodium persulfate	7775-27-1

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Sodium persulfate	7775-27-1	60 - 100%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) STOT SE 3 (H335) Ox. Sol. 3 (H272)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash off immediately with soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes eye irritation. Causes skin irritation. May cause allergic skin reaction. May cause allergic respiratory reaction. May cause respiratory irritation. Harmful if swallowed.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Oxidizer. May ignite combustibles. Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove sources of ignition. Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Remove sources of ignition. Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Avoid dust accumulations. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from combustibles. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Sodium persulfate	7775-27-1	0.01 mg/m^3	TWA: 0.1 mg/m^3

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Localized ventilation should be used to control dust levels.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Rubber apron.

Eye Protection Dust proof goggles.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	2.47
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	238.1 g/mol
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Avoid contact with readily oxidizable materials.
10.5. Incompatible materials
Avoid halogens. Contact with acids. Strong alkalis. Combustible materials.
10.6. Hazardous decomposition products
Oxides of sulfur. Oxygen. Sulfuric acid.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes eye irritation. Causes skin irritation. May cause allergic skin reaction. May cause allergic respiratory reaction. May cause respiratory irritation. Harmful if swallowed.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation

Sodium persulfate	7775-27-1	895 mg/kg (Rat) 1200 mg/kg 930 mg/kg 1000 mg/kg 920 mg/kg	> 10000 mg/kg (Rat)	19.0 mg/L (Rat) 4h > 5.1 mg/L (Rat) 4h

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled

Eye Contact Causes eye irritation.

Skin Contact Causes skin irritation. May cause an allergic skin reaction.

Ingestion Harmful if swallowed. Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Lung disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Sodium persulfate	7775-27-1	Causes skin irritation. (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Sodium persulfate	7775-27-1	Causes severe eye irritation (Rabbit)

Substances	CAS Number	Skin Sensitization
Sodium persulfate	7775-27-1	Skin sensitizer in guinea pig.

Substances	CAS Number	Respiratory Sensitization
Sodium persulfate	7775-27-1	May cause sensitization by inhalation

Substances	CAS Number	Mutagenic Effects
Sodium persulfate	7775-27-1	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Sodium persulfate	7775-27-1	Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Sodium persulfate	7775-27-1	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)

Substances	CAS Number	STOT - single exposure
Sodium persulfate	7775-27-1	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Sodium persulfate	7775-27-1	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Sodium persulfate	7775-27-1	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Sodium persulfate	7775-27-1	EC50 (72h) 116 mg/L (biomass) (Pseudokirchnerella subcapitata)	LC50 (96h) 163 mg/L (Oncorhynchus mykiss)	EC10 (18h) 36 mg/L (Pseudomonas putida)	EC50 (48h) 133 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Sodium persulfate	7775-27-1	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Sodium persulfate	7775-27-1	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Sodium persulfate	7775-27-1	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

This bag may contain residue of a hazardous material. Some authorities may regulate such containers as hazardous waste. Dispose of container according to national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1505
UN proper shipping name: Sodium Persulfate
Transport Hazard Class(es): 5.1
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1505
UN proper shipping name: Sodium Persulfate
Transport Hazard Class(es): 5.1
Packing Group: III
Environmental Hazards: Not applicable
EMS: EmS F-A, S-Q

IATA/ICAO

UN Number UN1505
UN proper shipping name: Sodium Persulfate
Transport Hazard Class(es): 5.1

Packing Group: III
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
1Z

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 21-Sep-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H272 - May intensify fire; oxidizer
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight

CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
OSHA
ECHA C&L

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-13003

Revision Date: 05-Jul-2016 **Revision Number:** 13

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-13003

Other means of Identification

Synonyms None

Hazardous Material Number: HM007648

Recommended use of the chemical and restrictions on use

Recommended Use Breaker

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute toxicity - Dermal	Category 4 - H312
Acute inhalation toxicity - vapor	Category 4 - H332
Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 2 - H401

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H312 - Harmful in contact with skin
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H332 - Harmful if inhaled
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Chlorous acid, sodium salt	7758-19-2
Sodium chloride	7647-14-5

Other hazards which do not result in classification
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Chlorous acid, sodium salt	7758-19-2	5 - 10%	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Corr. 1 (H318) STOT SE 3 (H335) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 3 (H412) Ox. Sol. 2 (H272)

Sodium chloride	7647-14-5	10 - 30%	Not Classified

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Seek immediate medical attention/advice. Suitable emergency eye wash facility should be immediately available

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. Harmful in contact with skin. Harmful if inhaled.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Product is not expected to burn unless all the water is boiled away. Use water spray to cool fire exposed surfaces. Decomposition in fire may produce harmful gases. If allowed to dry, this product is an oxidizer.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Wear self-contained breathing apparatus in enclosed areas. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder

contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from acids. Store away from reducing agents. Store away from direct sunlight. Keep from excessive heat. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Chlorous acid, sodium salt	7758-19-2	Not applicable	Not applicable
Sodium chloride	7647-14-5	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Organic vapor/acid gas/chlorine respirator.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Full protective chemical resistant clothing.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Clear tan
Odor: Mild chlorine
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	11.5-12.5
Freezing Point / Range	3-4 °C
Melting Point / Range	No data available
Boiling Point / Range	106 - 108 °C
Flash Point	No data available

Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.17 - 1.23
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

10.4. Conditions to avoid

Keep away from heat, sparks and flame. Avoid contact with organic materials. Avoid friction.

10.5. Incompatible materials

Prolonged contact with aluminum. Contact with metals. Organic matter. Contact with ammonia. All flammables, especially petroleum products, asphalt & other volatile flammables. Ammonium compounds. Strong acids.

10.6. Hazardous decomposition products

Chlorine.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. Harmful in contact with skin. Harmful if inhaled.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Chlorous acid, sodium salt	7758-19-2	165 mg/kg (Rat) 390 - 500 mg/kg (Rat) 212 – 284 mg/kg (Rat)	315 mg/kg (Rat) 134 mg/kg (Rabbit)	0.29 mg/L (Rat) 4h 230 mg/m³ (Rat) 4h
Sodium chloride	7647-14-5	3000 mg/kg-bw (rat)	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation	Harmful if inhaled. Causes severe respiratory irritation.
Eye Contact	Causes severe eye irritation which may damage tissue.
Skin Contact	Harmful in contact with skin. Causes severe burns.
Ingestion	Causes burns of the mouth, throat and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause adverse effects on the blood.

Exposure Levels

No data available

Interactive effects
Blood disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Chlorous acid, sodium salt	7758-19-2	Corrosive to skin (Rabbit)
Sodium chloride	7647-14-5	Non-irritating to the skin (Rabbit) Not a dermal irritant

Substances	CAS Number	Serious eye damage/irritation
Chlorous acid, sodium salt	7758-19-2	Corrosive to eyes (Rabbit)
Sodium chloride	7647-14-5	May cause mild eye irritation. (Rabbit)

Substances	CAS Number	Skin Sensitization
Chlorous acid, sodium salt	7758-19-2	Did not cause sensitization on laboratory animals (guinea pig)
Sodium chloride	7647-14-5	No information available Not confirmed to cause skin or respiratory sensitization.

Substances	CAS Number	Respiratory Sensitization
Chlorous acid, sodium salt	7758-19-2	No information available
Sodium chloride	7647-14-5	No information available

Substances	CAS Number	Mutagenic Effects
Chlorous acid, sodium salt	7758-19-2	Not regarded as mutagenic.
Sodium chloride	7647-14-5	No information available

Substances	CAS Number	Carcinogenic Effects
Chlorous acid, sodium salt	7758-19-2	Did not show carcinogenic effects in animal experiments
Sodium chloride	7647-14-5	Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Chlorous acid, sodium salt	7758-19-2	Animal testing did not show any effects on fertility. (fetotoxic and teratogenic effects).
Sodium chloride	7647-14-5	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Chlorous acid, sodium salt	7758-19-2	May cause respiratory irritation.
Sodium chloride	7647-14-5	No information available

Substances	CAS Number	STOT - repeated exposure
Chlorous acid, sodium salt	7758-19-2	Causes damage to organs through prolonged or repeated exposure if swallowed: (spleen) (Blood)
Sodium chloride	7647-14-5	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Chlorous acid, sodium salt	7758-19-2	Not applicable
Sodium chloride	7647-14-5	Not applicable

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Chlorous acid, sodium salt	7758-19-2	EC50 (72h) 9.09 mg/L (Skeletonema costatum) EC50 (72h) 0.2 mg/L (Pseudokirchnerella	LC50 (96h) 210 mg/L (Scophthalmus maximus) TLM96 290 mg/L (Oncorhynchus mykiss)	EC50 (3h) > 75 mg/L (activated sludge)	LC50 (48h) 50.67 mg/L (Acartia tonsa) TLM96 0.29 mg/L (Daphnia magna)

		subcapitata)	TLM96 208 mg/L (Lepomis macrochirus)		NOEC (22d) 25 ug/L (Daphnia magna)
Sodium chloride	7647-14-5	EC50 (120h) 2430 mg/L (Nitzschia sp.)	TLM96 > 1000 mg/L (Oncorhynchus mykiss) LC50 (96h) 5840 mg/L (Lepomis macrochirus) NOEC (33d) 252 mg/L (Pimephales promelas)	NOEC 5000 – 8000 mg/L (activated sludge) NOEC 292-584 mg/L (Escherichia coli)	TLM96 > 1,000,000 ppm (Mysidopsis bahia) LC50 (48h) 874-4136 mg/L (Daphnia magna) NOEC (21d) 314 mg/L (Daphnia pulex)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Chlorous acid, sodium salt	7758-19-2	The methods for determining biodegradability are not applicable to inorganic substances.
Sodium chloride	7647-14-5	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Chlorous acid, sodium salt	7758-19-2	No information available
Sodium chloride	7647-14-5	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Chlorous acid, sodium salt	7758-19-2	No information available
Sodium chloride	7647-14-5	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1908
UN proper shipping name: Chlorite Solution (14% Available Chlorine)
Transport Hazard Class(es): 8
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1908
UN proper shipping name: Chlorite Solution (14% Available Chlorine)
Transport Hazard Class(es): 8
Packing Group: III
Environmental Hazards: Not applicable
EMS: EmS F-A, S-B

IATA/ICAO

UN Number	UN1908
UN proper shipping name:	Chlorite Solution (14% Available Chlorine)
Transport Hazard Class(es):	8
Packing Group:	III
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
2X

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
H272 - May intensify fire; oxidizer
H301 - Toxic if swallowed
H310 - Fatal in contact with skin
H312 - Harmful in contact with skin
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H320 - Causes eye irritation
H330 - Fatal if inhaled
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H373 - May cause damage to organs through prolonged or repeated exposure if inhaled
H400 - Very toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
OSHA
ECHA C&L

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-16001

Revision Date: 05-Jul-2017 **Revision Number:** 11

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-16001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007655

Recommended use of the chemical and restrictions on use

Recommended Use Clay Stabilization Agent

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not classified

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician	Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Not applicable

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Not normally necessary.

Hand Protection Rubber gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	White
Odor:	Mild amine	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	7-9
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.07 - 1.091
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

Avoid contact with metals such as aluminum, tin, lead, brass, bronze, copper, and zinc.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Oxides of nitrogen. Hydrogen chloride. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Symptoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation None known.

Eye Contact None known.
Skin Contact None known.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability
Expected to be readily biodegradable

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects
Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-17001

Revision Date: 09-Nov-2017 **Revision Number:** 16

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-17001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007659

Recommended use of the chemical and restrictions on use

Recommended Use Corrosion Inhibitor

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Skin Sensitization	Category 1 - H317
Reproductive Toxicity	Category 1B - H360
Specific Target Organ Toxicity - (Single Exposure)	Category 1 - H370
Specific Target Organ Toxicity - (Repeated Exposure)	Category 2 - H373
Acute Aquatic Toxicity	Category 2 - H401
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H226 - Flammable liquid and vapor
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H360 - May damage fertility or the unborn child
H370 - Causes damage to organs
H373 - May cause damage to organs through prolonged or repeated exposure
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take action to prevent static discharges.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required

Response
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P307 + P311 - IF exposed: Call a POISON CENTER or doctor/physician
P314 - Get medical attention/advice if you feel unwell
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Diethylene glycol	111-46-6
Cinnamaldehyde	104-55-2
Amine oxides, cocoalkyldimethyl	61788-90-7
Methanol	67-56-1
Benzaldehyde	100-52-7
Alcohols, C12-16, ethoxylated	68551-12-2
Sodium iodide	7681-82-5

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	**CAS Number**	**PERCENT (w/w)**	**GHS Classification - Australia**
Diethylene glycol	111-46-6	30 - 60%	Acute Tox. 4 (H302) STOT RE 2 (H373)
Cinnamaldehyde	104-55-2	30 - 60%	Acute Tox. 4 (H312) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Aquatic Acute 2 (H401)
Amine oxides, cocoalkyldimethyl	61788-90-7	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400)
Methanol	67-56-1	10 - 30%	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Repr. 1B (H360) STOT SE 1 (H370) Flam. Liq. 2 (H225)
Benzaldehyde	100-52-7	5 - 10%	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Aquatic Acute 2 (H401) Flam. Liq. 4 (H227)
Alcohols, C12-16, ethoxylated	68551-12-2	1 - 5%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 3 (H412)
Sodium iodide	7681-82-5	1 - 5%	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335) STOT RE 1 (H372)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Get immediate medical attention. Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. May cause allergic skin reaction. Harmful if swallowed. May cause damage to internal organs. May cause damage to organs through prolonged or repeated exposure. Potential reproductive hazard. May cause birth defects.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Carbon dioxide, dry chemical, foam.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May be ignited by heat, sparks or flames Use water spray to cool fire exposed surfaces. Closed containers may explode in fire. Decomposition in fire may produce harmful gases. Runoff to sewer may cause fire or explosion hazard.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove sources of ignition. Use appropriate protective equipment. Wear self-contained breathing apparatus in enclosed areas. Avoid breathing vapors. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Remove ignition sources and work with non-sparking tools. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Remove sources of ignition. Ensure adequate ventilation. Avoid breathing vapors. Avoid contact with eyes, skin, or clothing. Wash hands after use. Launder contaminated clothing before reuse. Ground and bond containers when transferring from one container to another. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Keep from heat, sparks, and open flames. Store in a well ventilated area. Store locked up. Keep container closed when not in use. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Diethylene glycol	111-46-6	TWA: 23 ppm TWA: 100 mg/m³	Not applicable
Cinnamaldehyde	104-55-2	Not applicable	Not applicable
Amine oxides, cocoalkyldimethyl	61788-90-7	Not applicable	Not applicable
Methanol	67-56-1	TWA: 200 ppm TWA: 262 mg/m³ STEL: 250 ppm STEL: 328 mg/m³	TWA: 200 ppm STEL: 250 ppm
Benzaldehyde	100-52-7	Not applicable	Not applicable
Alcohols, C12-16, ethoxylated	68551-12-2	Not applicable	Not applicable
Sodium iodide	7681-82-5	Not applicable	TWA: 0.01 ppm

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Positive pressure self-contained breathing apparatus if methanol is released.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Rubber apron.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Yellow-orange
Odor: Cinnamon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.85 (10%)
Freezing Point / Range	-21 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	28.9 °C / 84 °F PMCC
Evaporation rate	No data available

Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.015
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

Keep away from heat, sparks and flame.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Ammonia. Oxides of nitrogen. Hydrocarbons. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes skin irritation. May cause allergic skin reaction. Harmful if swallowed. May cause damage to internal organs. May cause damage to organs through prolonged or repeated exposure. Potential reproductive hazard. May cause birth defects.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethylene glycol	111-46-6	12565 - 19600 mg/kg (Rat)	11890 - 13300 mg/kg (Rabbit)	> 4.6 mg/L (Rat) 4h
Cinnamaldehyde	104-55-2	2220 mg/kg (rat)	620 mg/kg (rabbit)	No data available
Amine oxides, cocoalkyldimethyl	61788-90-7	846 - 3873 mg/kg (Rat) 1000-1250 mg/kg (Rat)	4290 mg/kg (Rabbit)	No data available
Methanol	67-56-1	300 mg/kg-bw (human) < 790 to 13,000 mg/kg (rat)	1000 mg/kg-bw (human) 17,100 mg/kg (rabbit)	10 mg/L (human, 4h, vapor)
Benzaldehyde	100-52-7	1430 mg/kg (rat)	No information available	>1 <5 mg/L air (Rat, 4h, mist)
Alcohols, C12-16, ethoxylated	68551-12-2	1600 mg/kg	No data available	No data available
Sodium iodide	7681-82-5	4340 mg/kg (Rat) 3118 mg/kg (Rats) (Similar substance)	No data available	LCLo: 50000 mg/m³ (Mouse) 2h

Immediate, delayed and chronic health effects from exposure

Product Information Based on the collective toxicity of product ingredients, the mixture should be considered to cause the following:

Inhalation May cause respiratory irritation. May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.

Eye Contact Causes severe eye irritation which may damage tissue.

Skin Contact Causes skin irritation. May cause an allergic skin reaction.

Ingestion Harmful if swallowed. May cause central nervous system depression including headache, dizziness, drowsiness, muscular weakness, incoordination, slowed reaction time, fatigue blurred vision, slurred speech, giddiness, tremors and convulsions. May cause liver and kidney damage.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause reproductive system damage. Prolonged or repeated exposure may cause embryo and fetus toxicity.

Exposure Levels
No data available

Interactive effects
Skin disorders. Eye ailments.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Diethylene glycol	111-46-6	Non-irritating to the skin (Rabbit)
Cinnamaldehyde	104-55-2	Causes severe irritation and or burns (human)
Amine oxides, cocoalkyldimethyl	61788-90-7	Skin, rabbit: Causes moderate skin irritation.
Methanol	67-56-1	Non-irritating to the skin (Rabbit)
Benzaldehyde	100-52-7	Non-irritating to the skin (Rabbit)
Alcohols, C12-16, ethoxylated	68551-12-2	Causes skin irritation.
Sodium iodide	7681-82-5	Moderate dermal irritant (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Diethylene glycol	111-46-6	Non-irritating to the eye (Rabbit)
Cinnamaldehyde	104-55-2	Mild eye irritant. (human) (8 % solution)
Amine oxides, cocoalkyldimethyl	61788-90-7	Corrosive to eyes
Methanol	67-56-1	Non-irritating to the eye (Rabbit)
Benzaldehyde	100-52-7	Non-irritating to the eye (Rabbit)
Alcohols, C12-16, ethoxylated	68551-12-2	Causes severe eye irritation which may damage tissue.
Sodium iodide	7681-82-5	Moderately irritating to the eyes (Rabbit)

Substances	CAS Number	Skin Sensitization
Diethylene glycol	111-46-6	Did not cause sensitization on laboratory animals (guinea pig)
Cinnamaldehyde	104-55-2	Skin sensitizer in guinea pig.
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	Did not cause sensitization on laboratory animals (guinea pig)
Benzaldehyde	100-52-7	Not sensitizing in Guinea Pigs (Guinea Pig Maximisation Test and Open Epicutaneous Test, Sensitizing in Draize Test and Freund's Complete Adjuvant Test)
Alcohols, C12-16, ethoxylated	68551-12-2	Did not cause sensitization on laboratory animals
Sodium iodide	7681-82-5	Patch test on human volunteers did not demonstrate sensitization properties

Substances	CAS Number	Respiratory Sensitization
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No information available
Benzaldehyde	100-52-7	No information available
Alcohols, C12-16, ethoxylated	68551-12-2	No information available

Sodium iodide	7681-82-5	No information available

Substances	CAS Number	Mutagenic Effects
Diethylene glycol	111-46-6	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.
Cinnamaldehyde	104-55-2	In vitro tests did not show mutagenic effects.
Amine oxides, cocoalkyldimethyl	61788-90-7	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Methanol	67-56-1	The weight of evidence from available in vitro and in vivo studies indicates that this substance is not expected to be mutagenic.
Benzaldehyde	100-52-7	Not mutagenic in AMES Test. Negative in the chromosomal aberration assay In vitro tests have shown mutagenic effects In vivo tests did not show mutagenic effects.
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as mutagenic.
Sodium iodide	7681-82-5	In vitro tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Diethylene glycol	111-46-6	Did not show carcinogenic effects in animal experiments (Rat)
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No data of sufficient quality are available.
Benzaldehyde	100-52-7	Did not show carcinogenic effects in animal experiments (Rat) There was some evidence of carcinogenic activity in the forestomachs of mice.
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as carcinogenic.
Sodium iodide	7681-82-5	No information available

Substances	CAS Number	Reproductive toxicity
Diethylene glycol	111-46-6	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.
Cinnamaldehyde	104-55-2	Did not show teratogenic effects in animal experiments.
Amine oxides, cocoalkyldimethyl	61788-90-7	Did not show teratogenic effects in animal experiments. When tested at maternally toxic doses, no adverse effects on teratogenicity or development were observed.
Methanol	67-56-1	Experiments have shown reproductive toxicity effects on laboratory animals
Benzaldehyde	100-52-7	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as a reproductive and developmental toxicant.
Sodium iodide	7681-82-5	Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Diethylene glycol	111-46-6	No significant toxicity observed in animal studies at concentration requiring classification.
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	May cause respiratory irritation.
Methanol	67-56-1	May cause disorder and damage to the Central Nervous System (CNS)
Benzaldehyde	100-52-7	May cause respiratory irritation.
Alcohols, C12-16, ethoxylated	68551-12-2	No significant toxicity observed in animal studies at concentration requiring classification.
Sodium iodide	7681-82-5	No information available

Substances	CAS Number	STOT - repeated exposure
Diethylene glycol	111-46-6	Causes damage to organs through prolonged or repeated exposure: Kidney
Cinnamaldehyde	104-55-2	No significant toxicity observed in animal studies at concentration requiring classification.
Amine oxides, cocoalkyldimethyl	61788-90-7	No data of sufficient quality are available.
Methanol	67-56-1	No data of sufficient quality are available.
Benzaldehyde	100-52-7	No significant toxicity observed in animal studies at concentration requiring classification.
Alcohols, C12-16, ethoxylated	68551-12-2	No significant toxicity observed in animal studies at concentration requiring classification.
Sodium iodide	7681-82-5	Causes damage to organs through prolonged or repeated exposure: (Thyroid)

Substances	CAS Number	Aspiration hazard
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	Not applicable
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available

Methanol	67-56-1	Not applicable
Benzaldehyde	100-52-7	Not applicable
Alcohols, C12-16, ethoxylated	68551-12-2	Not applicable
Sodium iodide	7681-82-5	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Diethylene glycol	111-46-6	TGK (8d) 2700 mg/L (Scenedesmus quadricauda)	LC50 75200 mg/L (Pimephales promelas)	EC20 (30m) > 1995 mg/L (domestic activated sludge)	EC50 84000 mg/L (Daphnia magna) EC50 >10000 mg/L (Daphnia magna)
Cinnamaldehyde	104-55-2	EC50 (72 h) 2.1 mg/L (Skeletonema costatum)	LC50 (96 h) 2.38 mg/L (Scophthalmus maximus)	IC50 (48h) 131.2 mg/L (Tetrahymena pyriformis)	LC50 (48 h) 1.4 mg/L (Acartia tonsa)
Amine oxides, cocoalkyldimethyl	61788-90-7	ErC50 (72h) 0.29 mg/L (Selenastrum capricornutum) ErC50 (72h) 0.0235 mg/L (Scendesmus subspicatus) (similar substance)	LC50 (96h) 1.0–3.4 mg/L (Brachydanio rerio) LC50 (96h) 13.0 (Salmo gairdneri) LC50 (96h) 0.1-1 mg/L (Brachydanio rerio)	EC50 (3h) 240 mg/L (Pseudomonas putida) EC50 (3h) 13 mg/L (Activated sludge)	EC50 (48h) 2.9 mg/L (Daphnia magna) EC50 (48h) 0.083 mg/L (Daphnia magna) (similar substance)
Methanol	67-56-1	EC50 (96 h) =22000 mg/L (Pseudokirchnerella subcapitata) NOEC (8 d) =8000 mg/L (Scenedesmus quadricauda)	LC50 (96 h) =15400 mg/L (Lepomis macrochirus) EC50 (200 h) =14536 mg/L (Oryzias latipes)	IC50 (3h) > 1000 mg/L (activated sludge)	EC50 (96 h) =18260 mg/L (Dapnia magna) NOEC (21 d) =208 mg/L (Dapnia magna)
Benzaldehyde	100-52-7	NOEC (8d) 20 mg/L (Microcystis aeruginosa) NOEC (8d) 132 mg/L	LC50 (96 h) 1.07 mg/L (Lepomis macrochirus)	IC50 (3 h) 740 mg/L (Activated sludge)	EC50 (24 h) 50 mg/L (Daphnia magna)
Alcohols, C12-16, ethoxylated	68551-12-2	EC50 0.7 mg/L (Selenastrum capricornutum)	No information available	No information available	0.39 mg/L (Daphnia Magna)
Sodium iodide	7681-82-5	7 d Tox threshold: 2370 mg/L (Scenedesmus quadricauda, biomass) EC50(72h): 2588.7 mg/L (Skeletonema costatum)	LC50(96h): 3780 mg/L (Oncorhynchus mykiss) LC50(96h): > 100 mg/L (Scopthalmus maximus)	No information available	EC50(48h): 1.27 mg/L (Daphnia magna) EC50(48h): 575 mg/L (Acartia tonsa)

12.2. Persistence and degradability

No data is available on the product itself

Substances	CAS Number	Persistence and Degradability
Diethylene glycol	111-46-6	Readily biodegradable (90-100% @ 28d)
Cinnamaldehyde	104-55-2	Predicted to be readily biodegradable.
Amine oxides, cocoalkyldimethyl	61788-90-7	Readily biodegradable (81% @ 28d)
Methanol	67-56-1	Readily biodegradable (95% @ 20d)
Benzaldehyde	100-52-7	Readily biodegradable (>=95% @ 28d)
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	Not applicable

12.3. Bioaccumulative potential

No data is available on the product itself

Substances	CAS Number	Log Pow
Diethylene glycol	111-46-6	BCF: 100 (Leuciscus idus melanotus)
Cinnamaldehyde	104-55-2	Log Pow =1.4
Amine oxides, cocoalkyldimethyl	61788-90-7	Log Kow = 7.5
Methanol	67-56-1	Not Bioaccumulative; BCF=1
Benzaldehyde	100-52-7	Log Pow =1.1
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	-1.301

12.4. Mobility in soil

Substances	CAS Number	Mobility
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No information available
Benzaldehyde	100-52-7	No information available
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Incineration recommended in approved incinerator according to federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging
Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable
EMS: EmS F-E, S-E

IATA/ICAO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
•3Y

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 09-Nov-2017

Revision Note

SDS sections updated:
14

Full text of H-Statements referred to under sections 2 and 3

H225 - Highly flammable liquid and vapor
H226 - Flammable liquid and vapor
H227 - Combustible liquid
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H311 - Toxic in contact with skin
H312 - Harmful in contact with skin
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H331 - Toxic if inhaled
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H370 - Causes damage to organs
H372 - Causes damage to organs through prolonged or repeated exposure
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
NZ CCID

Disclaimer Statement

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-19001

Revision Date: 05-Jul-2016 **Revision Number:** 20

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-19001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007662

Recommended use of the chemical and restrictions on use

Recommended Use Crosslinker

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage/Irritation	Category 2 - H319
Reproductive Toxicity	Category 2 - H361

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H319 - Causes serious eye irritation
H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear eye protection/face protection
P281 - Use personal protective equipment as required

Response
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Disodium octaborate tetrahydrate	12008-41-2

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Disodium octaborate tetrahydrate	12008-41-2	60 - 100%	Eye Irrit. 2A (H319) Repr. 2 (H361)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure
Causes eye irritation Potential reproductive hazard. May cause birth defects.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical
Special exposure hazards in a fire
None anticipated

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation. Evacuate all persons from the area.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid creating or inhaling dust. Ensure adequate ventilation. Avoid contact with eyes, skin, or clothing. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Product has a shelf life of 60 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Disodium octaborate tetrahydrate	12008-41-2	Not applicable	2 mg/m^3

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment	If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection	If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Dust/mist respirator. (N95, P2/P3)
Hand Protection	Impervious rubber gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Dust proof goggles.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid	**Color**	White
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	7.3
Freezing Point / Range	No data available
Melting Point / Range	> 1000 °C
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	9.9E-17 pa @ 25°C
Vapor Density	No data available
Specific Gravity	1.7
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
None known.
10.6. Hazardous decomposition products
None known.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes eye irritation Potential reproductive hazard. May cause birth defects.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Disodium octaborate tetrahydrate	12008-41-2	2550 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rat) (similar substance)	>2 mg/L (dust, rat, 4 h) (similar substance)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation.

Eye Contact Causes eye irritation.

Skin Contact May cause mild skin irritation.

Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause reproductive system damage. Prolonged or repeated exposure may cause embryo and fetus toxicity.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Disodium octaborate tetrahydrate	12008-41-2	Not irritating to skin in rabbits. (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Disodium octaborate tetrahydrate	12008-41-2	Eye, rabbit: Causes moderate eye irritation

Substances	CAS Number	Skin Sensitization
Disodium octaborate tetrahydrate	12008-41-2	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Disodium octaborate tetrahydrate	12008-41-2	No information available

Substances	CAS Number	Mutagenic Effects
Disodium octaborate tetrahydrate	12008-41-2	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Disodium octaborate tetrahydrate	12008-41-2	Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Disodium octaborate tetrahydrate	12008-41-2	May impair fertility May cause birth defects (similar substances)

Substances	CAS Number	STOT - single exposure

Disodium octaborate tetrahydrate	12008-41-2	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	STOT - repeated exposure
Disodium octaborate tetrahydrate	12008-41-2	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Disodium octaborate tetrahydrate	12008-41-2	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Disodium octaborate tetrahydrate	12008-41-2	EC10 (3 d) 96.5 mg/L (Pseudokirchneriella subcapitata)	LC50 (96 h) 314.6 mg/L (Pimephales promelas) NOEC (34 d) 25.2 mg/L (Danio rerio)	EC50 (3 h) >39371 mg/L (activated sludge)	NOEC (21 d) 42.5 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Disodium octaborate tetrahydrate	12008-41-2	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Disodium octaborate tetrahydrate	12008-41-2	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Disodium octaborate tetrahydrate	12008-41-2	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
S5

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
H319 - Causes serious eye irritation

H361 - Suspected of damaging fertility or the unborn child

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
OSHA
ECHA C&L

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-19002

Revision Date: 05-Jul-2016 **Revision Number:** 19

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-19002

Other means of Identification

Synonyms None

Hazardous Material Number: HM007663

Recommended use of the chemical and restrictions on use

Recommended Use Crosslinker

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage/Irritation	Category 2 - H319
Reproductive Toxicity	Category 1B - H360
Specific Target Organ Toxicity - (Repeated Exposure)	Category 1 - H372

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H319 - Causes serious eye irritation
H360 - May damage fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear eye protection/face protection
P281 - Use personal protective equipment as required

Response
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P314 - Get medical attention/advice if you feel unwell

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Ulexite	1319-33-1
Ethylene glycol	107-21-1
Crystalline silica, quartz	14808-60-7

Other hazards which do not result in classification
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Ulexite	1319-33-1	30 - 60%	Eye Irrit. 2A (H319) Repr. 1 (H360)
Ethylene glycol	107-21-1	10 - 30%	Acute Tox. 4 (H302) STOT RE 1 (H372)
Crystalline silica, quartz	14808-60-7	1 - 5%	Carc. 2 (H351) STOT RE 1 (H372)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes	Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.
Skin	Wash off immediately with soap and plenty of water for at least 15 minutes while removing all contaminated clothing and shoes.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes eye irritation Potential reproductive hazard. May cause birth defects. Prolonged or repeated exposure may cause damage to organs. Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Contain spill with sand or other inert materials. Scoop up and remove. Isolate spill and stop leak where safe.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Avoid breathing mist. This product contains quartz, cristobalite, and/or tridymite which may become airborne without a visible cloud if this product becomes dry. Avoid breathing or creating dust. Use only with adequate ventilation to keep exposures below recommended exposure limits. Wear a NIOSH certified, European Standard EN 149, or equivalent respirator when using dried product. Ensure adequate ventilation. Material is slippery underfoot. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Ulexite	1319-33-1	Not applicable	Not applicable
Ethylene glycol	107-21-1	TWA: 10 mg/m³ TWA: 20 ppm TWA: 52 mg/m³ STEL: 40 ppm STEL: 104 mg/m³	Ceiling: 100 mg/m³ (aerosol only)
Crystalline silica, quartz	14808-60-7	TWA: 0.1 mg/m³	TWA: 0.025 mg/m³

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Organic vapor respirator.

Hand Protection Rubber gloves.
Skin Protection Rubber apron.
Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Odor: Odorless
Color Milky white
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.5 - 7.5
Freezing Point / Range	-34 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.45
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes eye irritation Potential reproductive hazard. May cause birth defects. Prolonged or repeated exposure may cause damage to organs. Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ulexite	1319-33-1	3493-6080 mg/kg (Rat) (similar substance) 3450 mg/kg (Male Rat) (similar substance)	> 2000 mg/kg (Rabbit) (similar substance)	> 2 mg/L (Rat) 4h (similar substance) > 2.12 mg/L (Rat) 4h (similar substance) > 2.04 mg/L (Rat) 4h (similar substance)
Ethylene glycol	107-21-1	4000 mg/kg (Rat) 7712 mg/kg (Rat) > 10000 mg/kg (Rat) 1670 mg/kg (Cat) 1400 – 1600 mg/kg (Human)	9530 µL/kg (Rabbit) > 3500 mg/kg (Mouse)	> 2.5 mg/L (Rat) 6h (saturated concentration)
Crystalline silica, quartz	14808-60-7	> 15000 mg/kg (human)	No information available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation. In high air concentrations: May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness. Inhaled crystalline silica in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (IARC, Group 1). There is sufficient evidence in experimental animals for the carcinogenicity of tridymite (IARC, Group 2A).

Breathing silica dust may cause irritation of the nose, throat, and respiratory passages. Breathing silica dust may not cause noticeable injury or illness even though permanent lung damage may be occurring. Inhalation of dust may also have serious chronic health effects (See "Chronic Effects/Carcinogenicity" subsection below).

Eye Contact Causes eye irritation.

Skin Contact May cause mild skin irritation.

Ingestion May be harmful if swallowed. In large amounts: May cause abdominal pain, vomiting,

nausea, and diarrhea. May cause heart, kidney and brain disorders.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause embryo and fetus toxicity. Prolonged or repeated exposure may cause reproductive system damage. Repeated overexposure may cause liver and kidney effects. Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling, and sometimes-fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness, and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop tuberculosis.

See "Inhalation" subsection above with respect to silicosis, cancer status and other data with possible relevance to human health. There is some evidence that breathing respirable crystalline silica or the disease silicosis is associated with an increased incidence of significant disease endpoints such as scleroderma (an immune system disorder manifested by scarring of the lungs, skin, and other internal organs) and kidney disease.

Exposure Levels
No data available

Interactive effects
Eye ailments. Skin disorders. Liver and kidney disorders. Individuals with respiratory disease, including but not limited to asthma and bronchitis, or subject to eye irritation, should not be exposed to quartz dust.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Ulexite	1319-33-1	Non-irritating to the skin (Rabbit) (similar substances)
Ethylene glycol	107-21-1	Non-irritating to the skin (Rabbit)
Crystalline silica, quartz	14808-60-7	Non-irritating to the skin

Substances	CAS Number	Serious eye damage/irritation
Ulexite	1319-33-1	Causes moderate eye irritation (Rabbit) (similar substances)
Ethylene glycol	107-21-1	Non-irritating to the eye (Rabbit)
Crystalline silica, quartz	14808-60-7	Mechanical irritation of the eyes is possible. No information available

Substances	CAS Number	Skin Sensitization
Ulexite	1319-33-1	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Ethylene glycol	107-21-1	Did not cause sensitization on laboratory animals (guinea pig) Patch test on human volunteers did not demonstrate sensitization properties
Crystalline silica, quartz	14808-60-7	No information available.

Substances	CAS Number	Respiratory Sensitization
Ulexite	1319-33-1	No information available
Ethylene glycol	107-21-1	No information available
Crystalline silica, quartz	14808-60-7	No information available

Substances	CAS Number	Mutagenic Effects
Ulexite	1319-33-1	In vitro tests did not show mutagenic effects (similar substances)
Ethylene glycol	107-21-1	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.
Crystalline silica, quartz	14808-60-7	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Ulexite	1319-33-1	Did not show carcinogenic effects in animal experiments (similar substances)
Ethylene glycol	107-21-1	Did not show carcinogenic effects in animal experiments
Crystalline silica, quartz	14808-60-7	Contains crystalline silica which may cause silicosis, a delayed and progressive lung disease. The IARC and NTP have determined there is sufficient evidence in humans of the carcinogenicity of crystalline silica with repeated respiratory exposure. Based on available scientific evidence, this

		substance is a threshold carcinogen with a mode of action involving indirect genotoxicity secondary to lung injury.

Substances	CAS Number	Reproductive toxicity
Ulexite	1319-33-1	Experiments have shown reproductive toxicity effects on laboratory animals (similar substances)
Ethylene glycol	107-21-1	Fetotoxic and teratogenic effects observed in experimental animals at concentrations that did not produce maternal toxicity.
Crystalline silica, quartz	14808-60-7	No information available

Substances	CAS Number	STOT - single exposure
Ulexite	1319-33-1	None under normal use conditions
Ethylene glycol	107-21-1	No significant toxicity observed in animal studies at concentration requiring classification.
Crystalline silica, quartz	14808-60-7	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Ulexite	1319-33-1	None under normal use conditions
Ethylene glycol	107-21-1	Causes damage to organs through prolonged or repeated exposure: (Kidney)
Crystalline silica, quartz	14808-60-7	Causes damage to organs through prolonged or repeated exposure if inhaled: (Lungs)

Substances	CAS Number	Aspiration hazard
Ulexite	1319-33-1	Not applicable
Ethylene glycol	107-21-1	No information available
Crystalline silica, quartz	14808-60-7	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Ulexite	1319-33-1	EC50 (72h) 1398.64 mg/L (Skeletonema costatum)	LC50 (96h) > 320 mg/L (Scophthalmus maximus) LC50 (96h) > 1100 mg/L (Oncorhynchus mykiss) LC50 (96h) > 1021 mg/L (Lepomis macrochirus) LD50 (28d) 65 mg/L (Oncorhynchus mykiss)	No information available	EC50 (48h) 7341.67 mg/L (Acartia tonsa) EC50 (48h) 133 mg/L (Daphnia magna)
Ethylene glycol	107-21-1	EC50 6500 - 13000 mg/L (Pseudokirchneriella subcapitata) TGK (8d) > 10000 mg/L (Scenedesmus quadricauda)	LC50 41000 mg/L (Oncorhynchus mykiss) LC50 (96h) 72860 mg/L (Pimephales promelas) NOEC (7d) 15380 mg/L (mortality) (Pimephales promelas)	TTC (16h) > 10000 mg/L (Pseudomonas putida) EC20 (30 m) > 1995 mg/L (activated sludge, domestic) (similar substance)	EC50 46300 mg/L (Daphnia magna) EC50 (48h) >100 mg/L (Daphnia magna) NOEC (7d) 8590 mg/L (reproduction) (Ceriodaphnia dubia)
Crystalline silica, quartz	14808-60-7	EC50 (72 h) =440 mg/L (Selenastrum capricornutum)	LL0 (96 h) =10000 mg/L (Danio rerio)	No information available	LL50 (24 h) >10000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Ulexite	1319-33-1	The methods for determining biodegradability are not applicable to inorganic substances.
Ethylene glycol	107-21-1	Readily biodegradable (100% @ 10d)
Crystalline silica, quartz	14808-60-7	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow

Ulexite	1319-33-1	0.175
Ethylene glycol	107-21-1	-1.36
Crystalline silica, quartz	14808-60-7	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Ulexite	1319-33-1	No information available
Ethylene glycol	107-21-1	No information available
Crystalline silica, quartz	14808-60-7	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2016

Revision Note

SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer if inhaled
H360 - May damage fertility or the unborn child
H372 - Causes damage to organs through prolonged or repeated exposure if swallowed
H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter

mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
OSHA
ECHA C&L

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-21003

Revision Date: 30-Sep-2015 **Revision Number:** 9

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-21003

Other means of Identification

Synonyms: None

Product Code: HM007806

Recommended use of the chemical and restrictions on use

Recommended Use Fluid Loss Additive

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton/Baroid Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: 61 (08) 9455 8300
Fax Number: 61 (08) 9455 5300

Product Emergency Telephone
Australia: + 61 1 800 686 951
Papua New Guinea: + 61 1 800 686 951
NewZealand: +64 800 451719

Fire, Police & Ambulance - Emergency Telephone
Australia: 000
Papua New Guinea: 000
New Zealand: 111

E-Mail address: fdunexchem@halliburton.com

Emergency phone number
+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous

Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word	Not Hazardous
Hazard Statements	Not Classified
Precautionary Statements	
Prevention	None
Response	None
Storage	None
Disposal	None

Contains Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

None known

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification	Not Classified
Risk Phrases	None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	If swallowed, induce vomiting immediately by giving two glasses of water and sticking fingers down throat; never give anything to an unconscious person. Get medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical
Special Exposure Hazards
Decomposition in fire may produce harmful gases. Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters
Special Protective Equipment for Fire-Fighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Spills of this product are very slippery.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Avoid dust accumulations.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Use good housekeeping in storage and work areas to prevent accumulation of dust. Close container when not in use. Store between 40.5 F (4.7 C) and 120.5 F (49 C). Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls	Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection	If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Dust/mist respirator. (N95, P2/P3)
Hand Protection	Normal work gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Powder	**Color:**	White to off white
Odor:	Sweet	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.24
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	388 °C / 730 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
Temperature over 440 F (240 C).
10.5. Incompatible Materials
Strong oxidizers. Strong alkalis.
10.6. Hazardous Decomposition Products
Toxic fumes. Aldehydes. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

LD50 Oral: > 5000 mg/kg; (Rat)

LD50 Dermal: > 2000 mg/kg; (Rabbit)

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact May cause mild eye irritation.

Skin Contact Prolonged or repeated contact may cause slight skin irritation.

Ingestion Irritation of the mouth, throat, and stomach. Large doses may cause nausea, vomiting and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances	NA	No information available	No information available	No information available	No information available

in concentrations above cut-off values according to the competent authority					

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Does not bioaccumulate

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-2120875

Revision Date: 25-Jun-2015 **Revision Number:** 3

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-2120875

Other means of Identification

Synonyms: None

Product Code: HM008041

Recommended use of the chemical and restrictions on use

Recommended Use Diverter

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton/Baroid Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: 61 (08) 9455 8300
Fax Number: 61 (08) 9455 5300

Product Emergency Telephone
Australia: + 61 1 800 686 951
Papua New Guinea: + 61 1 800 686 951
NewZealand: +64 800 451719

Fire, Police & Ambulance - Emergency Telephone
Australia: 000
Papua New Guinea: 000
New Zealand: 111

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word	Not Hazardous
Hazard Statements	Not Classified
Precautionary Statements	
Prevention	None
Response	None
Storage	None
Disposal	None

Contains Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

None known

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification	Not Classified
Risk Phrases	None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician	Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Slippery when wet.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Avoid dust accumulations.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Use good housekeeping in storage and work areas to prevent accumulation of dust. Close container when not in use. Store between 40.5 F (4.7 C) and 120.5 F (49 C). Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator

	is recommended:
	Dust/mist respirator. (N95, P2/P3)
Hand Protection	Normal work gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Beads	**Color:**	Green
Odor:	Odorless - Acidic	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	6-8
Freezing Point/Range	150-230 °C
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.16 - 1.20
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	300 °C / 572 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
Temperature over 440 F (240 C).
10.5. Incompatible Materials
Strong oxidizers. Strong alkalis.
10.6. Hazardous Decomposition Products
Toxic fumes. Aldehydes. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

LD50 Oral: No information available.
LD50 Dermal: No information available.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation None known.
Eye Contact None known.
Skin Contact None known.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Expected to be biodegradable

Substances	CAS Number	Persistence and Degradability

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Does not bioaccumulate

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 25-Jun-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-23001

Revision Date: 30-Sep-2015 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-23001

Other means of Identification

Synonyms: None

Product Code: HM007701

Recommended use of the chemical and restrictions on use

Recommended Use Friction Reducer

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical
Special Exposure Hazards
Not applicable.

Special protective equipment and precautions for fire fighters
Special Protective Equipment for Fire-Fighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Ground and bond containers when transferring from one container to another. Slippery when wet. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use. Keep from heat, sparks, and open flames. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection Normal work gloves.
Skin Protection Normal work coveralls.

Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Powder	**Color:**	White
Odor:	Slight	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	9
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	2
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical Stability

Stable

10.3. Possibility of Hazardous Reactions

Will Not Occur

10.4. Conditions to Avoid

None anticipated

10.5. Incompatible Materials

Strong oxidizers.

10.6. Hazardous Decomposition Products

Carbon monoxide and carbon dioxide. Ammonia.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion Large doses may cause nausea, vomiting and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Respiratory disorders. Skin disorders.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-23003

Revision Date: 31-Jul-2018 **Revision Number:** 8

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-23003

Other means of Identification

Synonyms None

Hazardous Material Number: HM008080

Recommended use of the chemical and restrictions on use

Recommended Use Friction Reducer

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Hydrotreated light petroleum distillate	64742-47-8
Ethoxylated branched C13 alcohol	78330-21-9
Sodium diacetate	126-96-5

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrotreated light petroleum distillate	64742-47-8	10 - 30%	Asp. Tox. 1 (H304)
Ethoxylated branched C13 alcohol	78330-21-9	1 - 5%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 3 (H412)
Sodium diacetate	126-96-5	1 - 5%	Eye Corr. 1 (H318)

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, move victim to fresh air and seek medical attention.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists. Remove contaminated clothing and launder before reuse.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire
Product is not expected to burn unless all the water is boiled away. Decomposition in fire may produce harmful gases. Use water spray to cool fire exposed surfaces.

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Spills of this product are very slippery. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove. Do NOT spread spilled product with water.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Use appropriate protective equipment. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Avoid breathing mist. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use. Store at temperatures between 40 and 90 F (5 and 35 C). Keep from freezing. Product has a shelf life of 6 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrotreated light petroleum distillate	64742-47-8	Not applicable	Not applicable
Ethoxylated branched C13 alcohol	78330-21-9	Not applicable	Not applicable
Sodium diacetate	126-96-5	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator is recommended:
Organic vapor respirator with a dust/mist filter. (A2P2/P3)
Hand Protection Impervious rubber gloves. Polyvinylchloride gloves.
Skin Protection Normal work coveralls.
Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Off white
Odor: Hydrocarbon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	5 - 8
Freezing Point / Range	No data available
Melting Point / Range	< 5 °C / < 41 °F
Boiling Point / Range	> 100 °C / 212 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	17.25 mmHg
Vapor Density	No data available
Specific Gravity	1.0 - 1.1
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	> 20.5 mm2/s
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Freezing conditions.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide. Oxides of nitrogen. Hydrogen cyanide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrotreated light	64742-47-8	>5000 mg/kg-bw (rat) (similar	>2000 mg/kg-bw (rabbit) (similar	>5.2 mg/L (rat, 4 h, vapor)

petroleum distillate		substance)	substance)	(similar substance)
Ethoxylated branched C13 alcohol	78330-21-9	1600 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rabbit) (similar substance)	>0.22 mg/L (rat, 4h, aerosol, saturated) (similar substance)
Sodium diacetate	126-96-5	5600 mg/kg (rat)	> 2000 mg/kg (rat)	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation If heated: May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.

Eye Contact In vitro tests indicate that the product is not an eye irritant.

Skin Contact Prolonged or repeated contact may cause skin irritation.

Ingestion May act as obstruction if swallowed. Aspiration can be a hazard if this material is swallowed.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Eye ailments. Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to the skin (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Skin, rabbit: Causes moderate skin irritation. (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to rabbit's eye (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Eye, rabbit: Causes severe eye irritation which may damage tissue. (similar substances)

Substances	CAS Number	Skin Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Sodium diacetate	126-96-5	Not regarded as a sensitizer.

Substances	CAS Number	Respiratory Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Based on available data, the classification criteria are not met.
Ethoxylated branched C13 alcohol	78330-21-9	Based on available data, the classification criteria are not met.
Sodium diacetate	126-96-5	No information available

Substances	CAS Number	Mutagenic Effects
Hydrotreated light petroleum distillate	64742-47-8	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Hydrotreated light petroleum distillate	64742-47-8	Did not show carcinogenic effects in animal experiments (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Hydrotreated light petroleum distillate	64742-47-8	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Sodium diacetate	126-96-5	(similar substances)

Substances	CAS Number	STOT - single exposure
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification.
Ethoxylated branched C13 alcohol	78330-21-9	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Sodium diacetate	126-96-5	No information available

Substances	CAS Number	STOT - repeated exposure
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Hydrotreated light petroleum distillate	64742-47-8	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Ethoxylated branched C13 alcohol	78330-21-9	Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrotreated light petroleum distillate	64742-47-8	ErL50(72 h)>10000 mg/L (Skeletonema costatum)	LC50(96 h)>10000 mg/L (Scophthalmus maximus) NOELR(28 d)>1000 mg/L (fish)	No information available	LC50(48 h)>10000 mg/L (Acartia tonsa) NOELR(21 d)=1000 mg/L (Daphnia magna)
Ethoxylated branched C13 alcohol	78330-21-9	IC50(72 h)=1-10 mg/L (Desmodesmus subspicatus)	LC50(96 h)=1-10 mg/L (Cyprinus carpio)	No information available	EC50(48 h)=1-10 mg/L (Daphnia magna) NOAEC (21d) 0.77 mg/L (Daphnia magna)
Sodium diacetate	126-96-5	EC50 (72 h) >1000 mg/L (Skeletonema costatum)	LC0 (96 h) >100 mg/L (Danio rerio) LC50 (96 h) 273 mg/L (Oreochromis mossambicus)	No information available	EC50 (48 h) >1000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Hydrotreated light petroleum distillate	64742-47-8	Readily biodegradable (68.1% @ 28d)
Ethoxylated branched C13 alcohol	78330-21-9	Readily biodegradable (> 60% @ 28d)
Sodium diacetate	126-96-5	No information available

12.3. Bioaccumulative potential

Bioaccumulation is unlikely

Substances	CAS Number	Log Pow
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethoxylated branched C13 alcohol	78330-21-9	Not Bioaccumulative; BCF = 12.7 - 237 L/Kg
Sodium diacetate	126-96-5	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility

Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethoxylated branched C13 alcohol	78330-21-9	No information available
Sodium diacetate	126-96-5	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS

US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 31-Jul-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H304 - May be fatal if swallowed and enters airways
H315 - Causes skin irritation
H318 - Causes serious eye damage
H412 - Harmful to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
OSHA

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-24001

Revision Date: 11-Jan-2017 **Revision Number:** 15

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-24001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007732

Recommended use of the chemical and restrictions on use

Recommended Use Stabilizer

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention None
Response None
Storage None
Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure
No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical
Special exposure hazards in a fire
Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid breathing vapors.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)
Hand Protection Normal work gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear to hazy
Odor:	Mild sulfur	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	8
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	106 °C / 224 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.29
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information
VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers. Hydrochloric acid
10.6. Hazardous decomposition products
Oxides of sulfur.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation None known.
Eye Contact May cause mild eye irritation.
Skin Contact Not irritating to skin in rabbits.
Ingestion Large doses may cause nausea, vomiting and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List	All components listed on inventory or are exempt.

(DSL)

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 11-Jan-2017

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-25003

Revision Date: 30-Sep-2015 **Revision Number:** 13

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-25003

Other means of Identification

Synonyms: None

Product Code: HM007670

Recommended use of the chemical and restrictions on use

Recommended Use Gelling Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

Dust can form an explosive mixture in air
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid creating or inhaling dust. Avoid contact with eyes, skin, or clothing. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Normal work gloves.

Skin Protection Normal work coveralls.

Eye Protection Wear safety glasses or goggles to protect against exposure.

Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: White to light straw
Odor: Bean
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	10.1
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.3
Water Solubility	Hydrolyzes
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	510 °C / 950 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
Strong oxidizers.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Follow all applicable community, national or regional regulations regarding waste management methods.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number:	Not restricted
UN Proper Shipping Name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-25005

Revision Date: 30-Sep-2015 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-25005

Other means of Identification

Synonyms: None

Product Code: HM007672

Recommended use of the chemical and restrictions on use

Recommended Use Gelling Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases. Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator is recommended:
Dust/mist respirator. (N95, P2/P3)

Hand Protection Normal work gloves.

Skin Protection Normal work coveralls.

Eye Protection Wear safety glasses or goggles to protect against exposure.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: Off white
Odor: Bean
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.5-7.5
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	> 93 °C / > 200 °F Cleveland Open Cup (COC)
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.42 - 1.47
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
Strong oxidizers.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above	NA	No data available	No data available	No data available

cut-off values according to the competent authority				

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact None known.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note

SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-30001

Revision Date: 05-Jul-2016 **Revision Number:** 11

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-30001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007676

Recommended use of the chemical and restrictions on use

Recommended Use Scale Inhibitor

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton/Baroid Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: 61 (08) 9455 8300
Fax Number: 61 (08) 9455 5300

Product Emergency Telephone
Australia: + 61 1 800 686 951
Papua New Guinea: + 61 1 800 686 951
NewZealand: +64 800 451719

Fire, Police & Ambulance - Emergency Telephone
Australia: 000
Papua New Guinea: 000
New Zealand: 111

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention None
Response None
Storage None
Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Not applicable

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing mist. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN

149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection	Butyl rubber gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear to slightly hazy amber
Odor:	Mild	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	6.49 - 7.49
Freezing Point / Range	-1.1 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C
Flash Point	> 95 °C / PMCC
Evaporation rate	< 1
Vapor Pressure	18 mmHg
Vapor Density	> 1
Specific Gravity	1.24
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	1.2
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide. Toxic monomer fumes.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye and skin contact.

Symptoms related to exposure
Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact Prolonged or repeated contact may cause slight skin irritation.
Ingestion In large amounts: Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Skin disorders. Eye ailments. Respiratory disorders.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability
Biodegradable.

Substances	CAS Number	Persistence and Degradability

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour

mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-32002

Revision Date: 07-Feb-2018 **Revision Number:** 19

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-32002

Other means of Identification

Synonyms None

Hazardous Material Number: HM007683

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 2 - H401

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H302 - Harmful if swallowed
H315 - Causes skin irritation
H318 - Causes serious eye damage
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear protective gloves/eye protection/face protection

Response
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician

Storage None

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1

Other hazards which do not result in classification
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	60 - 100%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401)

4. First aid measures

Description of necessary first aid measures

Inhalation	Under normal conditions, first aid procedures are not required.
Eyes	Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. Harmful if swallowed.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Wash hands after use. Avoid breathing vapors. Ensure adequate ventilation. Slippery when wet. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Keep container closed when not in use. Keep from heat, sparks, and open flames. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Not applicable	Not applicable
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls None known.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection Impervious rubber gloves. Polyvinylchloride gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Odor: Mild
Color Yellow
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.5 (1%)
Freezing Point / Range	-3 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	240 °C / 464 °F PMCC
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	> 10
Specific Gravity	0.98
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Strong oxidizers. Strong acids. Strong alkalis.

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes skin irritation. Harmful if swallowed.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	600 mg/kg (Rat) (similar substance)	> 5200 mg/kg (Rabbit) (similar substance)	> 0.22 mg/L (saturated concentration) (Rat) (similar substance)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	600 mg/kg (Rat) (similar substance)	> 5200 mg/kg (Rabbit) (similar substance)	>0.22 mg/L (saturated concentration) (Rat) (similar substance)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue.

Skin Contact Causes skin irritation.

Ingestion Harmful if swallowed. Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Causes skin irritation. (Rabbit) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Causes skin irritation. (Rabbit) (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Causes severe eye irritation (Rabbit) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Causes severe eye irritation (Rabbit) (similar substances)

Substances	CAS Number	Skin Sensitization

Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)

Substances	CAS Number	Respiratory Sensitization
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No information available
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No information available

Substances	CAS Number	Mutagenic Effects
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Did not show carcinogenic effects in animal experiments (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Did not show carcinogenic or teratogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Animal testing did not show any effects on fertility.
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	STOT - repeated exposure
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No adverse health effects are expected from swallowing.
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No adverse health effects are expected from swallowing.

12. Ecological Information

Ecotoxicity

Algae Toxicity ErC50 (72h): 2.58 - 3.44 mg/L (Desmodesmus subspicatus)

Acute Crustaceans Toxicity: EC50(48h): 1.45 - 1.79 mg/L (Daphnia magna)

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	EC50 (72h) 0.75 mg/L (Pseudokirchnerella subcapitata) (similar substance) EC50 (96h) 0.7 mg/L (Pseudokirchneriella subapitata) (similar substance) CD10 8 mg/L	LC50 (96h) 0.59 mg/L (Pleuronectes platessa) (similar substance) LC50 (96) 1.4 mg/L (Pimephales promelas) (similar substance) NOEC 4.4 mg/L (Pimephales promelas, juvenile)	ErC50 (16.9h) > 10 g/L (growth inhibition) (Pseudomonas putida) (similar substance)	EC50 (48h) 0.14 mg/L (Daphnia magna) (similar substance) EC50 (48h) 0.39 mg/L (Cerodaphnia dubia) (similar substance)

		(Pseudokirchneriella subapitata) EC10 2 mg/L (Brachionus calyciflorus)			
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	EC50 (72h) 0.75 mg/L (Pseudokirchnerella subcapitata) (similar substance) ErC50 (48h) 0.7 mg/L (Skeletonema costatum) EC10 9.79 mg/L (Selenastrum capricornutum) (similar substance) ErC50 1.1 mg/L (Scenedesmus subspicatus) (similar substance)	LC50 (96h) 0.59 mg/L (Pleuronectes platessa) (similar substance) LC50 (96h) 1.6 mg/L (Pimephales promelas) (similar substace) LC50 (96h) 3 mg/L (Brachydanio rerio) (similar substance)	ErC50 (16.9h) > 10 g/L (Pseudomonas putida) (similar substance)	EC50 (48h) 0.14 mg/L (Daphnia magna) (similar substance) EC50 (48h) 02 mg/L (Daphnia magna) (similar substance)

12.2. Persistence and degradability

Readily biodegradable

Substances	CAS Number	Persistence and Degradability
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Readily biodegradable (60% @ 28d) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Readily biodegradable (84% @ 28d) (similar substances)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Log Pow: 4.3 - 5.36 (estimated) BCF: 1.1 - 1.8 (fish, estimated)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Log Pow: 4.3 - 5.36 (estimated) BCF: 1.1 - 1.8 (fish, estimated)

12.4. Mobility in soil

Substances	CAS Number	Mobility
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	KOC = >4
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	KOC = >4

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number Not restricted

UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
•3Z

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 07-Feb-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed

H315 - Causes skin irritation
H318 - Causes serious eye damage

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
NZ CCID

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-32014

Revision Date: 31-Aug-2017 **Revision Number:** 3

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-32014

Other means of Identification

Synonyms None

Hazardous Material Number: HM008547

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against Consumer use

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Aspiration Toxicity	Category 1 - H304
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Reproductive Toxicity	Category 1B - H360
Acute Aquatic Toxicity	Category 2 - H401
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H226 - Flammable liquid and vapor
H304 - May be fatal if swallowed and enters airways
H315 - Causes skin irritation
H318 - Causes serious eye damage
H360 - May damage fertility or the unborn child
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take action to prevent static discharges.
P264 - Wash face, hands and any exposed skin thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required

Response
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P331 - Do NOT induce vomiting
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	CAS Number
Hydrotreated light petroleum distillate	64742-47-8
Ethanol	64-17-5
Fatty acids, tall-oil, ethoxylated	61791-00-2
C12-C15 Ethoxylated alcohols	68131-39-5
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4
Butyl alcohol	71-36-3

Methanol 67-56-1

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrotreated light petroleum distillate	64742-47-8	10 - 30%	Asp. Tox. 1 (H304)
Ethanol	64-17-5	10 - 30%	Eye Irrit. 2A (H319) Flam. Liq. 2 (H225)
Fatty acids, tall-oil, ethoxylated	61791-00-2	10 - 30%	Skin Irrit. 2 (H315) Eye Irrit. 2A (H319)
C12-C15 Ethoxylated alcohols	68131-39-5	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 3 (H412)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	10 - 30%	Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 3 (H412)
Butyl alcohol	71-36-3	5 - 10%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) STOT SE 3 (H335) Flam. Liq. 3 (H226)
Methanol	67-56-1	0.1 - 1%	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Repr. 1B (H360) STOT SE 1 (H370) Flam. Liq. 2 (H225)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Seek immediate medical attention/advice. Suitable emergency eye wash facility should be immediately available

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention.

Ingestion Get medical attention! If vomiting occurs, keep head lower than hips to prevent aspiration. Rinse mouth. Never give anything by mouth to an unconscious person. Following ingestion, onset of symptoms may be delayed by 12 to 24 hours. Admission to hospital should be the first priority even if symptoms are absent.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Potential reproductive hazard. May cause birth defects.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

Do NOT spray pool fires directly with water. A solid stream of water directed into hot burning liquid can cause splattering.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use appropriate protective equipment. Remove sources of ignition. Take precautionary measures against static discharges All equipment used when handling the product must be grounded Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Remove ignition sources and work with non-sparking tools.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Ensure adequate ventilation. Use appropriate protective equipment. Remove sources of ignition. Ground and bond containers when transferring from one container to another. Avoid contact with eyes, skin, or clothing.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep from heat, sparks, and open flames.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrotreated light petroleum distillate	64742-47-8	Not applicable	Not applicable
Ethanol	64-17-5	TWA: 1000 ppm TWA: 1880 mg/m^3	STEL: 1000 ppm
Fatty acids, tall-oil, ethoxylated	61791-00-2	Not applicable	Not applicable
C12-C15 Ethoxylated alcohols	68131-39-5	Not applicable	Not applicable
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not applicable	Not applicable
Butyl alcohol	71-36-3	50 ppm	TWA: 20 ppm

Methanol	67-56-1	TWA: 200 ppm TWA: 262 mg/m^3 STEL: 250 ppm STEL: 328 mg/m^3	TWA: 200 ppm STEL: 250 ppm

Appropriate engineering controls

Engineering Controls Ensure adequate ventilation, especially in confined areas

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Organic vapor respirator.

Hand Protection Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.

Skin Protection Wear impervious protective clothing, including boots, gloves, lab coat, apron, rain jacket, pants or coverall, as appropriate, to prevent skin contact.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Colorless to Light Amber
Odor: Mild hydrocarbon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	-44.2 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	34 °C / 93.2 °F
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.918
Water Solubility	No data available
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers. Strong acids. Strong alkalis.
10.6. Hazardous decomposition products
Carbon oxides. Oxides of nitrogen.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Skin contact. Eye contact. Inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes skin irritation. Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Potential reproductive hazard. May cause birth defects.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrotreated light petroleum distillate	64742-47-8	>5000 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rabbit) (similar substance)	>5.2 mg/L (rat, 4 h, vapor) (similar substance)
Ethanol	64-17-5	7060 mg/kg (Rat) 10,470 mg/kg (Rat)	> 15,800 mg/kg (Rabbit) 17,100 mg/kg (Rabbit)	124.7 mg/L (Rat) 4h
Fatty acids, tall-oil, ethoxylated	61791-00-2	> 6400 mg/kg (Rat)	No data available	No data available
C12-C15 Ethoxylated alcohols	68131-39-5	2 g/kg (Rat) 1600 mg/kg (Rat) > 5000 mg/kg (Rat)	> 2000 mg/kg (Rat) 2500 mg/kg (Rabbit)	No data available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	3500 mg/kg (Rat) > 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.219 mg/L (Mouse) 4h (similar substance)
Butyl alcohol	71-36-3	790 mg/kg (Rat)	3400 mg/kg (Rabbit)	> 17.6 mg/L (Rat) 4h
Methanol	67-56-1	300 mg/kg-bw (human) < 790 to 13,000 mg/kg (rat)	1000 mg/kg-bw (human) 17,100 mg/kg (rabbit)	10 mg/L (human, 4h, vapor)

Immediate, delayed and chronic health effects from exposure
Inhalation May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.
Eye Contact Causes severe eye irritation which may damage tissue.
Skin Contact Causes skin irritation.
Ingestion Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Ingestion of this product may cause blindness due to the presence of methanol.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause reproductive system damage. May cause birth defects.

Exposure Levels
No data available

Interactive effects
No data available

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to the skin (similar substances)
Ethanol	64-17-5	Not irritating to skin in rabbits.
Fatty acids, tall-oil, ethoxylated	61791-00-2	Irritating to skin.
C12-C15 Ethoxylated alcohols	68131-39-5	May cause moderate skin irritation. (Rabbit)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Skin, rabbit: Causes moderate skin irritation. (similar substances)
Butyl alcohol	71-36-3	Causes moderate skin irritation.
Methanol	67-56-1	Non-irritating to the skin (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to rabbit's eye (similar substances)
Ethanol	64-17-5	Causes moderate eye irritation (Rabbit)
Fatty acids, tall-oil, ethoxylated	61791-00-2	Irritating to eyes
C12-C15 Ethoxylated alcohols	68131-39-5	Risk of serious damage to eyes (Rabbit) (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Causes severe eye irritation (similar substances)
Butyl alcohol	71-36-3	Causes severe eye irritation
Methanol	67-56-1	Non-irritating to the eye (Rabbit)

Substances	CAS Number	Skin Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Ethanol	64-17-5	Did not cause sensitization on laboratory animals
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	Did not cause sensitization on laboratory animals (guinea pig)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Did not cause sensitization on laboratory animals (similar substances)
Butyl alcohol	71-36-3	Not confirmed to cause skin or respiratory sensitization.
Methanol	67-56-1	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	Did not cause sensitization on laboratory animals
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	No information available
Methanol	67-56-1	No information available

Substances	CAS Number	Mutagenic Effects
Hydrotreated light petroleum distillate	64742-47-8	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Ethanol	64-17-5	Not regarded as mutagenic.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	In vivo tests did not show mutagenic effects. In vitro tests did not show mutagenic effects.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Butyl alcohol	71-36-3	In vitro tests did not show mutagenic effects.
Methanol	67-56-1	The weight of evidence from available in vitro and in vivo studies indicates that this substance is not expected to be mutagenic.

Substances	CAS Number	Carcinogenic Effects

Hydrotreated light petroleum distillate	64742-47-8	Did not show carcinogenic effects in animal experiments (similar substances)
Ethanol	64-17-5	Did not show carcinogenic effects in animal experiments
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	Did not show carcinogenic effects in animal experiments
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not regarded as carcinogenic.
Butyl alcohol	71-36-3	No information available
Methanol	67-56-1	No data of sufficient quality are available.

Substances	**CAS Number**	**Reproductive toxicity**
Hydrotreated light petroleum distillate	64742-47-8	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Ethanol	64-17-5	Animal testing did not show any effects on fertility.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not a confirmed teratogen or embryotoxin.
Butyl alcohol	71-36-3	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.
Methanol	67-56-1	Experiments have shown reproductive toxicity effects on laboratory animals

Substances	**CAS Number**	**STOT - single exposure**
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification.
Ethanol	64-17-5	No significant toxicity observed in animal studies at concentration requiring classification.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No significant toxicity observed in animal studies at concentration requiring classification.
Butyl alcohol	71-36-3	May cause respiratory irritation.
Methanol	67-56-1	May cause disorder and damage to the Central Nervous System (CNS)

Substances	**CAS Number**	**STOT - repeated exposure**
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Ethanol	64-17-5	No significant toxicity observed in animal studies at concentration requiring classification.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No significant toxicity observed in animal studies at concentration requiring classification.
Butyl alcohol	71-36-3	No significant toxicity observed in animal studies at concentration requiring classification.
Methanol	67-56-1	No data of sufficient quality are available.

Substances	**CAS Number**	**Aspiration hazard**
Hydrotreated light petroleum distillate	64742-47-8	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Ethanol	64-17-5	Not applicable
Fatty acids, tall-oil, ethoxylated	61791-00-2	Not applicable
C12-C15 Ethoxylated alcohols	68131-39-5	No adverse health effects are expected from swallowing.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Methanol	67-56-1	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

Product is not classified as hazardous to the environment.

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrotreated light petroleum distillate	64742-47-8	ErL50(72 h)>10000 mg/L (Skeletonema costatum)	LC50(96 h)>10000 mg/L (Scophthalmus maximus) NOELC(28 d)>1000 mg/L (fish)	No information available	LC50(48 h)>10000 mg/L (Acartia tonsa) NOEC(21 d)=1000 mg/L (Daphnia magna)
Ethanol	64-17-5	No information available	LC50 > 100 mg/L (Pimephales promelas)	No information available	LC50 9268 - 14,221 mg/L (Daphnia magna) LC50 5012 mg/L (Ceridaphnia dubia) NOEC 9.6 mg/L (Daphnia magna)
Fatty acids, tall-oil, ethoxylated	61791-00-2	EC50 (72h) > 44 mg/L EC50 (72h) 2.5 mg/L (Skeletonema costatum)	LC50 (95h) 7.8 mg/L (Brachydanio rerio) LC50 (96h) 45 mg/L (Cyprinodon variegatus)	EC20 (180m) >1000 mg/L	EC50 (48h) 16 mg/L (Daphnia magna) EC50 (48h) 26.8 mg/L (Acartia tonsa)
C12-C15 Ethoxylated alcohols	68131-39-5	No information available	EC50 (48h) 0.39 mg/L (Ceriodaphnia dubia) NOEC (30d) 0.28 mg/L (Pimephales promelas) NOEC (16d) 0.16 mg/L(Lepomis macrochirus)	No information available	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	EC50 (72h) 2.2 mg/L (Scendesmus subspicatus) (similar substance)	LC50 (96h) 6.7 mg/L (Danio rerio) (similar substance)	No information available	LC50 (21d) = 0.1 mg/L (Daphnia magna) LC50 (48h) = 2.15 mg/L
Butyl alcohol	71-36-3	EC50 (96h) 225 mg/L (Pseudokirchnerella subcapitata)	LC50 (96h) 1376 mg/L (Pimephales promelas)	No information available	EC50 (48h) 1328 mg/L (Daphnia magna) NOEC (21d) 4.1 mg/L (Daphnia magna) EC50 (21d) 18 mg/L (Daphnia magna)
Methanol	67-56-1	EC50 (96 h) =22000 mg/L (Pseudokirchnerella subcapitata) NOEC (8 d) =8000 mg/L (Scenedesmus quadricauda)	LC50 (96 h) =15400 mg/L (Lepomis macrochirus) EC50 (200 h) =14536 mg/L (Oryzias latipes)	IC50 (3h) > 1000 mg/L (activated sludge)	EC50 (96 h) =18260 mg/L (Dapnia magna) NOEC (21 d) =208 mg/L (Dapnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Hydrotreated light petroleum distillate	64742-47-8	Readily biodegradable (68.1% @ 28d)
Ethanol	64-17-5	No information available
Fatty acids, tall-oil, ethoxylated	61791-00-2	Readily biodegradable (74% @ 28d)
C12-C15 Ethoxylated alcohols	68131-39-5	Readily biodegradable
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Readily biodegradable (77% @ 28d)
Butyl alcohol	71-36-3	Biodegradable. (92% @ 20d)
Methanol	67-56-1	Readily biodegradable (95% @ 20d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	-0.32
Fatty acids, tall-oil, ethoxylated	61791-00-2	MW > 700
C12-C15 Ethoxylated alcohols	68131-39-5	3
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	3.2 (estimated)

Butyl alcohol	71-36-3	1
Methanol	67-56-1	Not Bioaccumulative; BCF=1

12.4. Mobility in soil

Substances	CAS Number	Mobility
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	No information available
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	KOC = 72
Methanol	67-56-1	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IATA/ICAO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

•3Y

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 31-Aug-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H225 - Highly flammable liquid and vapor
H226 - Flammable liquid and vapor
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H304 - May be fatal if swallowed and enters airways
H311 - Toxic in contact with skin
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H331 - Toxic if inhaled
H335 - May cause respiratory irritation
H360 - May damage fertility or the unborn child
H370 - Causes damage to organs
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%

LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

FE-2

Revision Date: 16-Apr-2015 **Revision Number:** 28

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name FE-2

Other means of Identification

Synonyms: None

Product Code: HM000682

Recommended use of the chemical and restrictions on use

Recommended Use Iron Control Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage / Eye Irritation	Category 2 - H319

Label elements, including precautionary statements

Hazard Pictograms



Signal Word Warning

Hazard Statements H319 - Causes serious eye irritation

Precautionary Statements

Prevention P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear eye protection/face protection

Response P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention

Storage None

Disposal None

Contains

Substances	**CAS Number**
Citric acid	77-92-9

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Xi - Irritant.

Risk Phrases R36 Irritating to eyes.

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Citric acid	77-92-9	60 - 100%	Eye Irrit. 2A (H319)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes eye irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases. Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from alkalis. Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Citric acid	77-92-9	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Nitrile gloves. (>= 0.35 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Normal work coveralls.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	2 - 2.2
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
upper flammability limit	65
lower flammability limit	8
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.665
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	1000 °C / 1832 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	192.13
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical Stability

Stable

10.3. Possibility of Hazardous Reactions

Will Not Occur

10.4. Conditions to Avoid

None anticipated

10.5. Incompatible Materials

Strong alkalis. Strong oxidizers.

10.6. Hazardous Decomposition Products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure

Most Important Symptoms/Effects

Causes eye irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Citric acid	77-92-9	5400 mg/kg (Rat) 5790 mg/kg (Mouse) 11,700 mg/kg (Rat)	> 2000 mg/kg	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes eye irritation.

Skin Contact May cause mild skin irritation.

Ingestion Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Citric acid	77-92-9	Not irritating to skin in rabbits.

Substances	CAS Number	Eye damage/irritation
Citric acid	77-92-9	Causes severe eye irritation.

Substances	CAS Number	Skin Sensitization
Citric acid	77-92-9	Patch test on human volunteers did not demonstrate sensitization properties

Substances	CAS Number	Respiratory Sensitization
Citric acid	77-92-9	No information available

Substances	CAS Number	Mutagenic Effects
Citric acid	77-92-9	Did not show mutagenic effects in animal experiments

Substances	CAS Number	Carcinogenic Effects
Citric acid	77-92-9	Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Citric acid	77-92-9	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Citric acid	77-92-9	No data of sufficient quality are available.

Substances	CAS Number	STOT - repeated exposure
Citric acid	77-92-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Citric acid	77-92-9	No adverse health effects are expected from swallowing.

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Citric acid	77-92-9	NOEC (8d) 425 mg/L (cell density) (Scenedesmus quadricauda) LOEC (8d) >80 mg/L (Microcystis aeruginosa)	LC50 (96h) 1516 mg/L (Lepomis macrochirus) LC50 (48h) 440 mg/L (Leuciscus idus melanotus) LC50 (96h) >100 mg/L (Pimephales promelas)	TT (72h) 485 mg/L (Entosiphon sulcatum)	TLM96 100-330 ppm (Crangon crangon) EC50 (24h) 1535 mg/L (Daphnia magna) LC50 (48h) 160 mg/L (Daphnia magna) EC50 (48h) >50 mg/L (Daphnia magna)

12.2. Persistence and degradability

Biodegradable.

Substances	CAS Number	Persistence and Degradability
Citric acid	77-92-9	Readily biodegradable (97% @ 28d)

12.3. Bioaccumulative potential

Does not bioaccumulate

Substances	CAS Number	Log Pow
Citric acid	77-92-9	-1.61 to -1.80

12.4. Mobility in soil

Substances	CAS Number	Mobility
Citric acid	77-92-9	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual

contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number:	Not restricted
UN Proper Shipping Name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

16. Other information

Date of preparation or review

Revision Date: 16-Apr-2015

Revision Note Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
R36 - Irritating to eyes

Full text of H-Statements referred to under sections 2 and 3
H319 - Causes serious eye irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50

– Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

HC-2A

Revision Date: 12-Jun-2018 **Revision Number:** 2

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name HC-2A

Other means of Identification

Synonyms None

Hazardous Material Number: HM008835

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 2 - H401
Chronic Aquatic Toxicity	Category 2 - H411

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H318 - Causes serious eye damage
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention
P273 - Avoid release to the environment
P280 - Wear eye protection/face protection

Response
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P391 - Collect spillage

Storage None

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Inner salt of alkyl amines	Proprietary

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Inner salt of alkyl amines	Proprietary	10 - 30%	Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Rinse mouth with water many times. Get medical attention if symptoms occur

Symptoms caused by exposure
Causes severe eye irritation which may damage tissue.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Use water spray to cool fire exposed surfaces. Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Inner salt of alkyl amines	Proprietary	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection	If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Dust/mist respirator. (N95, P2/P3)
Hand Protection	Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.
Skin Protection	Wear protective clothing appropriate for the work environment.
Eye Protection	Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions	Eyewash fountains and safety showers must be easily accessible.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear light amber
Odor:	Surfactant	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	6.5-7.5
Freezing Point / Range	0 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C / 212 °F
Flash Point	> 100 °C / > 212 °F PMCC
Evaporation rate	No data available
Vapor Pressure	< 17.5 mmHg
Vapor Density	No data available
Specific Gravity	1.12
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Oxides of nitrogen. Carbon monoxide and carbon dioxide. Hydrogen chloride.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure	Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Inner salt of alkyl amines	Proprietary	>5000 mg/kg-bw (rat)	>2000 mg/kg-bw (rat)	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue. May cause corneal injury.

Skin Contact May cause mild skin irritation.

Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Inner salt of alkyl amines		Not irritating to skin in rabbits.

Substances	CAS Number	Serious eye damage/irritation
Inner salt of alkyl amines		Causes severe eye irritation (Rabbit)

Substances	CAS Number	Skin Sensitization
Inner salt of alkyl amines		Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Inner salt of alkyl amines		No information available

Substances	CAS Number	Mutagenic Effects
Inner salt of alkyl amines		In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Inner salt of alkyl amines		Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Inner salt of alkyl amines		Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Inner salt of alkyl amines		No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Inner salt of alkyl amines		No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Inner salt of alkyl amines		Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Inner salt of alkyl amines	Proprietary	EC50 (96 h) 0.55 mg/L (Desmodesmus subspicatus) EC50 (72 h) 17.2 mg/L (Scenedesmus subspicatus) EC50 (72 h) 9.86 mg/L (Scenedesmus subspicatus) EC50 (72 h) 30 mg/L (Scenedesmus subspicatus)	LC50 (96 h) 2 mg/L (Brachydanio rerio) NOEC (28 d) 16 mg/L (Oncorhynchus mykiss)	No information available	EC50 (48 h) 6.5 mg/L (Daphnia magna) NOEC (21 d) 0.9 mg/L (Daphnia magna) NOEC (21 d) 0.932 mg/L (Daphnia magna) NOEC (21 d) 2.98 mg/L (Daphnia magna) NOEC (21 d) 0.03 mg/L (Daphnia magna) NOEC (21 d) 0.065 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Inner salt of alkyl amines	Proprietary	Readily biodegradable (>90% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Inner salt of alkyl amines	Proprietary	Log Pow =0.9

12.4. Mobility in soil

Substances	CAS Number	Mobility
Inner salt of alkyl amines	Proprietary	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Follow all applicable community, national or regional regulations regarding waste management methods.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN3082
UN proper shipping name: Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es): 9
Packing Group: III
Environmental Hazards: Marine Pollutant

IMDG/IMO

UN Number	UN3082
UN proper shipping name:	Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es):	9
Packing Group:	III
Environmental Hazards:	Marine Pollutant
EMS:	EmS F-A, S-F

IATA/ICAO

UN Number	UN3082
UN proper shipping name:	Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es):	9
Packing Group:	III
Environmental Hazards:	Marine Pollutant

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 12-Jun-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H318 - Causes serious eye damage
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

HYDROCHLORIC ACID

Revision Date: 20-Jun-2016 **Revision Number:** 40

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name HYDROCHLORIC ACID

Other means of Identification

Synonyms None

Hazardous Material Number: HM000911

Recommended use of the chemical and restrictions on use

Recommended Use Solvent

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute inhalation toxicity - vapor	Category 3 - H331
Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Substances/mixtures corrosive to metal	Category 1 - H290

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H331 - Toxic if inhaled
H335 - May cause respiratory irritation

Precautionary Statements

Prevention
P103 - Read label before use
P234 - Keep only in original container
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P390 - Absorb spillage to prevent material damage

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
P406 - Store in corrosive resistant container with a resistant inner liner.

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Hydrochloric acid	7647-01-0

Other hazards which do not result in classification
Chronic exposure to corrosive fumes/gases may cause erosion of the teeth followed by jaw necrosis. Bronchial irritation with chronic cough and frequent attacks of pneumonia are common. Gastrointestinal disturbances may also be seen
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrochloric acid	7647-01-0	30 - 60%	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Eye Corr. 1 (H318)

			STOT SE 3 (H335) Met. Corr. 1 (H290)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation. Harmful if inhaled.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May form explosive mixtures with strong alkalis. Decomposition in fire may produce harmful gases. Reaction with steel and certain other metals generates flammable hydrogen gas. Do not allow runoff to enter waterways.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from alkalis. Store in a cool well ventilated area. Keep container closed when not in use. Store locked up. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrochloric acid	7647-01-0	5 ppm	TWA: 2 ppm (Ceiling)

Appropriate engineering controls
Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Acid gas respirator.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.
Skin Protection Full protective chemical resistant clothing. Rubber boots
Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions Eyewash fountains and safety showers must be easily accessible.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties
Physical State: Liquid
Color Clear colorless
Odor: Pungent acrid
Odor Threshold: No information available

Property	Values	Remarks/ - Method
pH:	0.8	
Freezing Point / Range	-46 °C	
Melting Point / Range	No data available	
Boiling Point / Range	110 °C / 230 °F	
Flash Point	No data available	

Evaporation rate	No data available
Vapor Pressure	26
Vapor Density	No data available
Specific Gravity	1.18
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	36.5
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong alkalis.
10.6. Hazardous decomposition products
Flammable hydrogen gas. Chlorine. Hydrogen sulfide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation. Harmful if inhaled.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrochloric acid	7647-01-0	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation	Harmful if inhaled. Causes severe respiratory irritation.
Eye Contact	Causes eye burns
Skin Contact	Causes severe burns. Did not cause sensitization on laboratory animals (guinea pig)
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrochloric acid	7647-01-0	Causes severe burns Causes severe skin irritation with tissue destruction.

Substances	CAS Number	Serious eye damage/irritation
Hydrochloric acid	7647-01-0	Causes severe burns Causes severe eye irritation. Will damage tissue.

Substances	CAS Number	Skin Sensitization
Hydrochloric acid	7647-01-0	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Hydrochloric acid	7647-01-0	No information available

Substances	CAS Number	Mutagenic Effects
Hydrochloric acid	7647-01-0	Not regarded as mutagenic. In vitro tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Hydrochloric acid	7647-01-0	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Hydrochloric acid	7647-01-0	Embryo and fetotoxicity has been observed in female rats exposed to maternally toxic levels of hydrogen chloride (450 mg/m^3, 1hr.). When tested at maternally toxic doses, no adverse effects on fertility, teratogenicity, or development were observed.

Substances	CAS Number	STOT - single exposure
Hydrochloric acid	7647-01-0	May cause respiratory irritation. No information available

Substances	CAS Number	STOT - repeated exposure
Hydrochloric acid	7647-01-0	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Hydrochloric acid	7647-01-0	Not applicable

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrochloric acid	7647-01-0	No information available	LC50 282 mg/L (Gambusia affinis) LC50 20.5 mg/L (Lepomis macrochirus) LC50 (96h) 3.25 – 3.5 (pH) (Lepomis macrochirus)	EC50 (3h) >= 5 and <= 5.5 (pH) (Activated sludge, domestic)	EC50 (48 h) 4.92 mg/L (Daphnia magna)

12.2. Persistence and degradability
The methods for determining biodegradability are not applicable to inorganic substances.

Substances	CAS Number	Persistence and Degradability
Hydrochloric acid	7647-01-0	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow

Hydrochloric acid	7647-01-0	LogKow -2.65

12.4. Mobility in soil

Substances	CAS Number	Mobility
Hydrochloric acid	7647-01-0	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number UN1789
UN proper shipping name: Hydrochloric Acid Solution
Transport Hazard Class(es): 8
Packing Group: II
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances) This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL) All components listed on inventory or are exempt.

Poisons Schedule number

S6

International Agreements

Montreal Protocol - Ozone Depleting Substances: Does not apply
Stolkhom Convention - Persistent Organic Pollutants: Does not apply
Rotterdam Convention - Prior Informed Consent: Does not apply

Basel Convention - Hazardous Waste: Does not apply

16. Other information

Date of preparation or review

Revision Date: 20-Jun-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation
H331 - Toxic if inhaled
H332 - Harmful if inhaled

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

NITROGEN LIQUEFIED

Revision Date: 29-Aug-2017 **Revision Number:** 30

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name NITROGEN LIQUEFIED

Other means of Identification

Synonyms None

Hazardous Material Number: HM001654

Recommended use of the chemical and restrictions on use

Recommended Use Fluid

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Gases under pressure.	Refrigerated liquefied gas - H281

Label elements, including precautionary statements

Hazard Pictograms

Signal Word WARNING

Hazard Statements: H281 - Contains refrigerated gas; may cause cryogenic burns or injury

Precautionary Statements

Prevention	P282 - Wear cold insulating gloves and either face shield or eye protection.
Response	P336 - Thaw frosted parts with lukewarm water. Do no rub affected area P315 - Get immediate medical advice/attention
Storage	P403 - Store in a well-ventilated place
Disposal	None

Contains

Substances	**CAS Number**
Nitrogen	7727-37-9

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Nitrogen	7727-37-9	60 - 100%	Refrigerated Liquefied Gas Compressed gas (H280)

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, move victim to fresh air and seek medical attention.
Eyes	In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.
Skin	For exposure to liquid, immediately warm frostbite area with warm water (not to exceed 105 F or 41 C). In case of massive exposure, remove clothing while showering with warm water. Get medical attention.
Ingestion	Get immediate medical attention.

Symptoms caused by exposure

Reduces oxygen available for breathing. May cause freeze burns.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Containers may explode (due to the build-up of pressure) when exposed to extreme heat

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions
None known.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Ensure adequate ventilation. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Nitrogen	7727-37-9	1000 ppm	:

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
In high concentrations, supplied air respirator or a self-contained breathing apparatus.
Hand Protection Substantial leather work gloves.
Skin Protection Normal work coveralls.
Eye Protection None known.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear colorless
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	-210 °C
Melting Point / Range	No data available
Boiling Point / Range	-195 °C / -319 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	608
Vapor Density	0.97
Specific Gravity	0.8
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	28
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
None known.
10.6. Hazardous decomposition products
None known.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Reduces oxygen available for breathing. May cause freeze burns.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Nitrogen	7727-37-9	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation	Reduces oxygen available for breathing.
Eye Contact	Contact with liquid causes frostbite.
Skin Contact	Contact of material on skin may result in frostbite.
Ingestion	Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Nitrogen	7727-37-9	Contact with liquid causes frostbite.

Substances	CAS Number	Serious eye damage/irritation
Nitrogen	7727-37-9	Non-irritating to the eye

Substances	CAS Number	Skin Sensitization
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Respiratory Sensitization
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Mutagenic Effects
Nitrogen	7727-37-9	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Reproductive toxicity
Nitrogen	7727-37-9	No information available

Substances	CAS Number	STOT - single exposure
Nitrogen	7727-37-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Nitrogen	7727-37-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Nitrogen	7727-37-9	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Nitrogen	7727-37-9	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Nitrogen	7727-37-9	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow

Nitrogen	7727-37-9	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Nitrogen	7727-37-9	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable
EMS: EmS F-C, S-V

IATA/ICAO

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

2T

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.

New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 29-Aug-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H281 - Contains refrigerated gas; may cause cryogenic burns or injury

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

POTASSIUM CHLORIDE

Revision Date: 04-Sep-2015 **Revision Number:** 22

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name POTASSIUM CHLORIDE

Other means of Identification

Synonyms: None

Product Code: HM001200

Recommended use of the chemical and restrictions on use

Recommended Use Brine

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure
No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
All standard fire fighting media
Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical
Special Exposure Hazards
Not applicable.

Special protective equipment and precautions for fire fighters
Special Protective Equipment for Fire-Fighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Product has a shelf life of 60 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Respiratory Protection Dust/mist respirator. (N95, P2/P3)
Hand Protection Normal work gloves.
Skin Protection Normal work coveralls.
Eye Protection Dust proof goggles.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid	**Color:**	White to gray
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	~7
Freezing Point/Range	771 °C
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.99
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	74.55
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
None known.
10.6. Hazardous Decomposition Products
None known.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according	NA	No data available	No data available	No data available

to the competent authority				

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea. Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable.

Substances	CAS Number	Eye damage/irritation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable.

Substances	CAS Number	Skin Sensitization
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Respiratory Sensitization
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Mutagenic Effects
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Carcinogenic Effects
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Reproductive toxicity

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	STOT - single exposure
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	STOT - repeated exposure
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Aspiration hazard
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Bury in a licensed landfill according to federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging
Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number:	Not restricted
UN Proper Shipping Name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

16. Other information

Date of preparation or review

Revision Date: 04-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

SAND - LOCAL

Revision Date: 01-Feb-2019 **Revision Number:** 2

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name SAND - LOCAL

Other means of Identification

Synonyms None

Hazardous Material Number: HM008704

Recommended use of the chemical and restrictions on use

Recommended Use Proppant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Carcinogenicity	Category 1A - H350
Specific Target Organ Toxicity - (Repeated Exposure)	Category 1 - H372

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H350 - May cause cancer by inhalation
H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required

Response
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P314 - Get medical attention/advice if you feel unwell

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Crystalline silica, quartz	14808-60-7

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Crystalline silica, quartz	14808-60-7	60 - 100%	Carc. 1A (H350) STOT RE 1 (H372)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

Skin Flush skin with large amounts of water. If irritation persists, get medical attention.

Ingestion Rinse mouth with water many times. Get medical attention, if symptoms occur

Symptoms caused by exposure
This product contains a suspected carcinogen. Causes damage to organs through prolonged or repeated exposure. Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

None - does not burn.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

None anticipated

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

None known.

6.3. Methods and material for containment and cleaning up

Collect using dustless method and hold for appropriate disposal. Consider possible toxic or fire hazards associated with contaminating substances and use appropriate methods for collection, storage and disposal.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

This product contains quartz, cristobalite, and/or tridymite which may become airborne without a visible cloud. Avoid breathing dust. Avoid creating dusty conditions. Use only with adequate ventilation to keep exposure below recommended exposure limits. Wear a NIOSH certified, European Standard En 149, or equivalent respirator when using this product. Material is slippery when wet.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Use good housekeeping in storage and work areas to prevent accumulation of dust. Close container when not in use. Product has a shelf life of 36 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Crystalline silica, quartz	14808-60-7	TWA: 0.1 mg/m^3	TWA: 0.025 mg/m^3

Appropriate engineering controls

Engineering Controls A well ventilated area to control dust levels.

Personal protective equipment (PPE)

Personal Protective Equipment	If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection	Wear a NIOSH certified, European Standard EN 149 (FFP2/FFP3), AS/NZS 1715, or equivalent respirator when using this product.
Hand Protection	Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.
Skin Protection	Wear clothing appropriate for the work environment. Dusty clothing should be laundered before reuse. Use precautionary measures to avoid creating dust when removing or laundering clothing.
Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid	**Color**	White to tan
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	No data available
Melting Point / Range	No data available
Pour Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	2.63 - 2.67
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	65 g/mole
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Hydrofluoric acid.

10.6. Hazardous decomposition products
Amorphous silica may transform at elevated temperatures to tridymite (870 C) or cristobalite (1470 C).

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
This product contains a suspected carcinogen. Causes damage to organs through prolonged or repeated exposure. Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Crystalline silica, quartz	14808-60-7	> 15000 mg/kg (human)	No data available	No data available

Immediate, delayed and chronic health effects from exposure
Inhalation Breathing silica dust may cause irritation of the nose, throat, and respiratory passages. Breathing silica dust may not cause noticeable injury or illness even though permanent lung damage may be occurring. Inhalation of dust may also have serious chronic health effects (See "Chronic Effects/Carcinogenicity" subsection below).

Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity This product contains a suspected carcinogen. Causes damage to organs through prolonged or repeated exposure. Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling, and sometimes-fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness, and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop tuberculosis.

Exposure Levels
No data available

Interactive effects
Individuals with respiratory disease, including but not limited to asthma and bronchitis, or subject to eye irritation, should not be exposed to quartz dust.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Crystalline silica, quartz	14808-60-7	Non-irritating to the skin

Substances	CAS Number	Serious eye damage/irritation
Crystalline silica, quartz	14808-60-7	Non-irritating to the eye No information available

Substances	CAS Number	Skin Sensitization
Crystalline silica, quartz	14808-60-7	No information available.

Substances	CAS Number	Respiratory Sensitization

Crystalline silica, quartz	14808-60-7	No information available

Substances	CAS Number	Mutagenic Effects
Crystalline silica, quartz	14808-60-7	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Crystalline silica, quartz	14808-60-7	Contains crystalline silica which may cause silicosis, a delayed and progressive lung disease. The IARC and NTP have determined there is sufficient evidence in humans of the carcinogenicity of crystalline silica with repeated respiratory exposure.

Substances	CAS Number	Reproductive toxicity
Crystalline silica, quartz	14808-60-7	No information available

Substances	CAS Number	STOT - single exposure
Crystalline silica, quartz	14808-60-7	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Crystalline silica, quartz	14808-60-7	Causes damage to organs through prolonged or repeated exposure if inhaled: (Lungs)

Substances	CAS Number	Aspiration hazard
Crystalline silica, quartz	14808-60-7	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Crystalline silica, quartz	14808-60-7	EC50(72 h)=440 mg/L (Pseudokirchneriella subcapitata)	LL0(96 h)=10000 mg/L (Danio rerio)	No information available	LL50(24 h)>10000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Crystalline silica, quartz	14808-60-7	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Bioaccumulation
Crystalline silica, quartz	14808-60-7	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Crystalline silica, quartz	14808-60-7	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information
Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 01-Feb-2019

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H350 - May cause cancer by inhalation
H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

CERAMIC PROP

Revision Date: 07-Jun-2018 **Revision Number:** 12

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name CERAMIC PROP

Other means of Identification

Synonyms None

Hazardous Material Number: HM004805

Recommended use of the chemical and restrictions on use

Recommended Use Proppant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Carcinogenicity	Category 1A - H350
Specific Target Organ Toxicity - (Repeated Exposure)	Category 1 - H372

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H350 - May cause cancer by inhalation
H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P281 - Use personal protective equipment as required

Response
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P314 - Get medical attention/advice if you feel unwell

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Crystalline silica, cristobalite	14464-46-1

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Crystalline silica, cristobalite	14464-46-1	10 - 30%	Carc. 1A (H350) STOT RE 1 (H372)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure
Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

None - does not burn.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Not applicable

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

None known.

6.3. Methods and material for containment and cleaning up

Collect using dustless method and hold for appropriate disposal. Consider possible toxic or fire hazards associated with contaminating substances and use appropriate methods for collection, storage and disposal.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

This product contains quartz, cristobalite, and/or tridymite which may become airborne without a visible cloud. Avoid breathing dust. Avoid creating dusty conditions. Use only with adequate ventilation to keep exposure below recommended exposure limits. Wear a NIOSH certified, European Standard En 149, or equivalent respirator when using this product. Material is slippery when wet.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Store locked up. Store in a cool, dry location. Use good housekeeping in storage and work areas to prevent accumulation of dust. Close container when not in use.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Crystalline silica, cristobalite	14464-46-1	TWA: 0.1 mg/m^3	TWA: 0.025 mg/m^3

Appropriate engineering controls

Engineering Controls Use approved industrial ventilation and local exhaust as required to maintain exposures below applicable exposure limits.

Personal protective equipment (PPE)

Personal Protective Equipment	If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection	Wear a NIOSH certified, European Standard EN 149 (FFP2/FFP3), AS/NZS 1715, or equivalent respirator when using this product.
Hand Protection	Normal work gloves.
Skin Protection	Wear clothing appropriate for the work environment. Dusty clothing should be laundered before reuse. Use precautionary measures to avoid creating dust when removing or laundering clothing.
Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid	**Color**	Gray to tan
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	No data available
Melting Point / Range	No data available
Pour Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	3.1
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Hydrofluoric acid.

10.6. Hazardous decomposition products

Amorphous silica may transform at elevated temperatures to tridymite (870 C) or cristobalite (1470 C).

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Breathing crystalline silica can cause lung disease, including silicosis and lung cancer. Crystalline silica has also been associated with scleroderma and kidney disease.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Crystalline silica, cristobalite	14464-46-1	> 15000 mg/kg (human) (similar substance)	No information available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation Inhaled crystalline silica in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (IARC, Group 1). There is sufficient evidence in experimental animals for the carcinogenicity of tridymite (IARC, Group 2A).

Breathing silica dust may cause irritation of the nose, throat, and respiratory passages. Breathing silica dust may not cause noticeable injury or illness even though permanent lung damage may be occurring. Inhalation of dust may also have serious chronic health effects (See "Chronic Effects/Carcinogenicity" subsection below).

Eye Contact May cause mechanical irritation to eye.

Skin Contact None known.

Ingestion None known.

Chronic Effects/Carcinogenicity Silicosis: Excessive inhalation of respirable crystalline silica dust may cause a progressive, disabling, and sometimes-fatal lung disease called silicosis. Symptoms include cough, shortness of breath, wheezing, non-specific chest illness, and reduced pulmonary function. This disease is exacerbated by smoking. Individuals with silicosis are predisposed to develop tuberculosis.

Cancer Status: The International Agency for Research on Cancer (IARC) has determined that crystalline silica inhaled in the form of quartz or cristobalite from occupational sources can cause lung cancer in humans (Group 1 - carcinogenic to humans) and has determined that there is sufficient evidence in experimental animals for the carcinogenicity of tridymite (Group 2A - possible carcinogen to humans). Refer to IARC Monograph 68, Silica, Some Silicates and Organic Fibres (June 1997) in conjunction with the use of these minerals. The National Toxicology Program classifies respirable crystalline silica as "Known to be a human carcinogen". Refer to the 9th Report on Carcinogens (2000). The American Conference of Governmental Industrial Hygienists (ACGIH) classifies crystalline silica, quartz, as a suspected human carcinogen (A2). There is some evidence that breathing respirable crystalline silica or the disease silicosis is associated with an increased incidence of significant disease endpoints such as scleroderma (an immune system disorder manifested by scarring of the lungs, skin, and other internal organs) and kidney disease.

Exposure Levels

No data available

Interactive effects

Individuals with respiratory disease, including but not limited to asthma and bronchitis, or subject to eye irritation, should not be exposed to quartz dust.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Crystalline silica, cristobalite	14464-46-1	Non-irritating to the skin

Substances	CAS Number	Serious eye damage/irritation
Crystalline silica, cristobalite	14464-46-1	Mechanical irritation of the eyes is possible.

Substances	CAS Number	Skin Sensitization
Crystalline silica, cristobalite	14464-46-1	No information available

Substances	CAS Number	Respiratory Sensitization
Crystalline silica, cristobalite	14464-46-1	No information available

Substances	CAS Number	Mutagenic Effects
Crystalline silica, cristobalite	14464-46-1	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Crystalline silica, cristobalite	14464-46-1	Contains crystalline silica which may cause silicosis, a delayed and progressive lung disease. The IARC and NTP have determined there is sufficient evidence in humans of the carcinogenicity of crystalline silica with repeated respiratory exposure. Based on available scientific evidence, this substance is a threshold carcinogen with a mode of action involving indirect genotoxicity secondary to lung injury.

Substances	CAS Number	Reproductive toxicity
Crystalline silica, cristobalite	14464-46-1	No information available

Substances	CAS Number	STOT - single exposure
Crystalline silica, cristobalite	14464-46-1	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Crystalline silica, cristobalite	14464-46-1	Causes damage to organs through prolonged or repeated exposure if inhaled: (Lungs)

Substances	CAS Number	Aspiration hazard
Crystalline silica, cristobalite	14464-46-1	Not applicable

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
Product is not classified as hazardous to the environment.

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Crystalline silica, cristobalite	14464-46-1	No information available	LL0(96 h)=10000 mg/L (Danio rerio)	No information available	LL50(24 h)>10000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Crystalline silica, cristobalite	14464-46-1	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Bioaccumulation

Crystalline silica, cristobalite	14464-46-1	Not bioaccumulative

12.4. Mobility in soil

Substances	CAS Number	Mobility
Crystalline silica, cristobalite	14464-46-1	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or

Chemicals	assessment certificate.
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 07-Jun-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H350 - May cause cancer by inhalation
H372 - Causes damage to organs through prolonged or repeated exposure if inhaled

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

Coil Tubing Hydraulic Fracturing System SDS

HALLIBURTON

SAFETY DATA SHEET

ACETIC ACID 60%

Revision Date: 19-Mar-2015 **Revision Number:** 9

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name ACETIC ACID 60%

Other means of Identification

Synonyms: None

Product Code: HM004481

Recommended use of the chemical and restrictions on use

Recommended Use Solvent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion / irritation	Category 1 - H314
Serious Eye Damage / Eye Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word Danger

Hazard Statements
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation
H226 - Flammable liquid and vapor

Precautionary Statements

Prevention
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P240 - Ground/Bond container and receiving equipment
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take precautionary measures against static discharge
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301+ P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing
P312 - Call a POISON CENTER or doctor/physician if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Acetic acid	64-19-7

Other hazards which do not result in classification
None known

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification C - Corrosive.

Risk Phrases
R10 Flammable.
R34 Causes burns.
R37 Irritating to respiratory system.

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Acetic acid	64-19-7	60 - 100%	Skin Corr. 1A (H314) Eye Corr. 1 (H318) STOT SE 3 (H335) Flam. Liq. 3 (H226)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Use water spray to cool fire exposed surfaces. Decomposition in fire may produce harmful gases. Do not allow runoff to enter waterways.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and

remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 24 months. Store locked up.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Acetic acid	64-19-7	TWA: 10 ppm TWA: 25 mg/m^3 STEL: 15 ppm STEL: 37 mg/m^3	TWA: 10 ppm STEL: 15 ppm

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Respiratory Protection Organic vapor/acid gas respirator.

Hand Protection Impervious rubber gloves.

Skin Protection Full protective chemical resistant clothing.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid **Color:** Clear

Odor: Acrid **Odor Threshold:** No information available

Property Remarks/ - Method	Values
pH:	1.38
Freezing Point/Range	16 °C
Melting Point/Range	No data available
Boiling Point/Range	117 °C / 244 °F
Flash Point	55 °C / 131 °F PMCC
upper flammability limit	16%
lower flammability limit	5.4%
Evaporation rate	No data available
Vapor Pressure	11.7 mmHg @ 20 C
Vapor Density	No data available
Specific Gravity	1.05
Water Solubility	Soluble in water
Solubility in other solvents	No data available

Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	60.6 (g/mole)
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
Keep away from heat, sparks and flame.
10.5. Incompatible Materials
Strong alkalis.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Acetic acid	64-19-7	3310 mg/kg (Rat) 600 mg/kg (Rabbit) 4960 mg/kg (Mouse)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4h

Immediate, delayed and chronic health effects from exposure

Inhalation	Causes severe respiratory irritation.
Eye Contact	Causes eye burns.
Skin Contact	Causes skin burns which may not be immediately painful or visible.
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Acetic acid	64-19-7	Corrosive to skin

Substances	CAS Number	Eye damage/irritation
Acetic acid	64-19-7	Corrosive to eyes

Substances	CAS Number	Skin Sensitization
Acetic acid	64-19-7	Not regarded as a sensitizer.

Substances	CAS Number	Respiratory Sensitization
Acetic acid	64-19-7	No information available

Substances	CAS Number	Mutagenic Effects
Acetic acid	64-19-7	In vivo tests did not show mutagenic effects. In vitro tests did not show mutagenic effects

Substances	CAS Number	Carcinogenic Effects
Acetic acid	64-19-7	Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Acetic acid	64-19-7	Did not show teratogenic effects in animal experiments. Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Acetic acid	64-19-7	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Acetic acid	64-19-7	Not applicable due to corrosivity of the substance.

Substances	CAS Number	Aspiration hazard
Acetic acid	64-19-7	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Acetic acid	64-19-7	EC50 90 mg/L (Microcystis aeruginosa) EC50 (72h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Skeletonema costatum)	LC50 79 mg/L (Pimephales promelas) LC50 75 mg/L (Pimephales promelas) LC50 (96h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Oncorhynchus mykiss)	NOEC (16h) 1150 mg/L (Pseudomonas putida)	EC50 47 mg/L (Daphnia magna) LC50 32 mg/L (Artemia salina) EC50 (48h) > 1000 mg/L (>300.82 mg/L – acetate ion) (Daphnia magna) NOEC (21d) 31.4 - 37.9 mg/L (Daphnia magna) (reproduction)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Acetic acid	64-19-7	Readily biodegradable (99% @ 7d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Acetic acid	64-19-7	-0.17 BCF = 3.16 (Calculated)

12.4. Mobility in soil

Substances	CAS Number	Mobility
Acetic acid	64-19-7	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number: UN2790
UN Proper Shipping Name: Acetic Acid Solution
Transport Hazard Class(es): 8
Packing Group: II
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number
S6

16. Other information

Date of preparation or review

Revision Date: 19-Mar-2015

Revision Note Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
R10 Flammable.
R34 Causes burns.
R35 Causes severe burns.
R37 Irritating to respiratory system.

Full text of H-Statements referred to under sections 2 and 3
H226 - Flammable liquid and vapor
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

BE-9

Revision Date: 13-Oct-2017 **Revision Number:** 20

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name BE-9

Other means of Identification

Synonyms None

Hazardous Material Number: HB006583

Recommended use of the chemical and restrictions on use

Recommended Use Biocide

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 1 - H400
Chronic Aquatic Toxicity	Category 2 - H411

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H400 - Very toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P391 - Collect spillage

Storage
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Tributyl tetradecyl phosphonium chloride	81741-28-8

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Tributyl tetradecyl phosphonium chloride	81741-28-8	5 - 10%	Acute Tox. 4 (H302) Acute Tox. 2 (H330) Skin Corr. 1B (H314) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases. Do not allow runoff to enter waterways. Use water spray to cool fire exposed surfaces.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Wash hands after use. Launder contaminated clothing before reuse. Do NOT consume food, drink, or tobacco in contaminated areas.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep container closed when not in use. Store away from direct sunlight. Store in a dry location. Store in a manner to prevent commingling with incompatible materials. Store away from alkalis. Store away from reducing agents. Store locked up.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Tributyl tetradecyl phosphonium chloride	81741-28-8	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Neoprene gloves. (>= 0.75 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Wear impervious protective clothing, including boots, gloves, lab coat, apron, rain jacket, pants or coverall, as appropriate, to prevent skin contact.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Clear colorless
Odor: Slight
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6-8
Freezing Point / Range	-8 - -10 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C / 212 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.95 - 1.0
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Reducing agents. Strong alkalis.

10.6. Hazardous decomposition products

Chlorine. Phosphorus acids. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Tributyl tetradecyl phosphonium chloride	81741-28-8	= 611 mg/kg (rat)	No data of sufficient quality are available	> 0.908 mg/L (rat, 4hr, mist)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue. May cause eye burns.

Skin Contact Causes severe skin irritation with tissue destruction.

Ingestion Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Lung disorders. Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Tributyl tetradecyl phosphonium chloride	81741-28-8	Causes burns (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Tributyl tetradecyl phosphonium chloride	81741-28-8	Causes severe eye irritation which may damage tissue. (Rabbit)

Substances	CAS Number	Skin Sensitization
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Respiratory Sensitization
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Mutagenic Effects
Tributyl tetradecyl phosphonium chloride	81741-28-8	No data of sufficient quality are available.

Substances	CAS Number	Carcinogenic Effects
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	Reproductive toxicity
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	STOT - single exposure
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

Substances	CAS Number	STOT - repeated exposure
Tributyl tetradecyl phosphonium chloride	81741-28-8	No data of sufficient quality are available.

Substances	CAS Number	Aspiration hazard
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available	LC50 (96 h) 0.46 mg/L (Oncorhynchus mykiss) LC50 (96 h) 0.06 mg/L (Lepomis macrochirus)	No information available	EC50 (48 h) 0.025 mg/L (Daphnia sp.)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Tributyl tetradecyl phosphonium chloride	81741-28-8	(0% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Tributyl tetradecyl phosphonium chloride	81741-28-8	< 3

12.4. Mobility in soil

Substances	CAS Number	Mobility
Tributyl tetradecyl phosphonium chloride	81741-28-8	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations. Incineration recommended in approved incinerator according to federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant

IMDG/IMO

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant
EMS:	EmS F-A, S-B

IATA/ICAO

UN Number	UN2922
UN proper shipping name:	Corrosive Liquid, Toxic, N.O.S. (contains Tributyl Tetradecyl Phosphonium Chloride)
Transport Hazard Class(es):	8, (6.1)
Packing Group:	II
Environmental Hazards:	Marine Pollutant

Special precautions during transport
None

HazChem Code
2X

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 13-Oct-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H330 - Fatal if inhaled
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects
H411 - Toxic to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

CAUSTIC SODA LIQUID

Revision Date: 16-Apr-2015 **Revision Number:** 8

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name CAUSTIC SODA LIQUID

Other means of Identification

Synonyms None

Hazardous Material Number: HM005652

Recommended use of the chemical and restrictions on use

Recommended Use pH Control

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Substances/mixtures corrosive to metal.	Category 1 - H290

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Precautionary Statements

Prevention
P234 - Keep only in original packaging.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P363 - Wash contaminated clothing before reuse
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P390 - Absorb spillage to prevent material damage
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Sodium hydroxide	1310-73-2

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Sodium hydroxide	1310-73-2	30 - 60%	Skin Corr. 1A (H314) Eye Corr. 1 (H318) STOT SE 3 (H335) Met. Corr. 1 (H290)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes	Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.
Skin	Remove contaminated clothing and launder before reuse. Destroy or properly dispose of contaminated shoes. In case of contact, immediately flush skin with plenty of soap and water for at least 30 minutes and remove contaminated clothing, shoes and leather goods immediately. Get medical attention immediately.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

May cause eye and skin burns. May cause respiratory irritation. Causes severe skin irritation with tissue destruction. Causes severe eye irritation which may damage tissue.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May form explosive mixtures with strong acids. Reaction with steel and certain other metals generates flammable hydrogen gas.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and remove. Isolate spill and stop leak where safe.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from acids. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Sodium hydroxide	1310-73-2	2 mg/m³	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Full protective chemical resistant clothing.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Clear colorless
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	14
Freezing Point / Range	12 °C
Melting Point / Range	No data available
Boiling Point / Range	144 °C / 291 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	13 mmHg
Vapor Density	No data available
Specific Gravity	1.52
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available

Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	40
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong acids. Peroxides. Halogenated compounds. Amphoteric metals such as aluminum, magnesium, lead, tin, or zinc.
10.6. Hazardous decomposition products
None known.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
May cause eye and skin burns. May cause respiratory irritation. Causes severe skin irritation with tissue destruction. Causes severe eye irritation which may damage tissue.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hydroxide	1310-73-2	Not applicable due to corrosivity of the substance.	Not applicable due to corrosivity of the substance.	Not applicable due to corrosivity of the substance.

Immediate, delayed and chronic health effects from exposure

Inhalation	Causes severe respiratory burns.
Eye Contact	Causes severe eye burns.
Skin Contact	Causes severe burns.
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Sodium hydroxide	1310-73-2	Causes severe burns

Substances	CAS Number	Serious eye damage/irritation
Sodium hydroxide	1310-73-2	Causes severe eye burns (Rabbit)

Substances	CAS Number	Skin Sensitization
Sodium hydroxide	1310-73-2	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Sodium hydroxide	1310-73-2	No information available

Substances	CAS Number	Mutagenic Effects
Sodium hydroxide	1310-73-2	Did not show mutagenic effects in animal experiments In vitro tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Sodium hydroxide	1310-73-2	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Sodium hydroxide	1310-73-2	No information available

Substances	CAS Number	STOT - single exposure
Sodium hydroxide	1310-73-2	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Sodium hydroxide	1310-73-2	No significant toxicity observed in animal studies at concentration requiring classification. Not applicable due to corrosivity of the substance.

Substances	CAS Number	Aspiration hazard
Sodium hydroxide	1310-73-2	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Sodium hydroxide	1310-73-2	No information available	LC50(48h) 189 mg/L (Leuciscus idus melanotus) LLC50(48h) 189 mg/L (Leuciscus melanotus) LC50(24h) 145 mg/L (Poecilia reticulate) LC50(96h) 125 mg/L (Gambusia affinis) LOEL(150 d) = 25 mg/L (Lebistes reticulatus)	No information available	EC50 (48h) 40.4 mg/L (Ceriodaphnia sp.)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Sodium hydroxide	1310-73-2	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Sodium hydroxide	1310-73-2	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Sodium hydroxide	1310-73-2	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information
Australia ADG

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable
EMS:	EmS F-A, S-B

IATA/ICAO

UN Number	UN1824
UN proper shipping name:	Sodium Hydroxide Solution
Transport Hazard Class(es):	8
Packing Group:	II
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 16-Apr-2015

Revision Note

Full text of H-Statements referred to under sections 2 and 3
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-14003

Revision Date: 27-Sep-2016 **Revision Number:** 11

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-14003

Other means of Identification

Synonyms None

Hazardous Material Number: HM007651

Recommended use of the chemical and restrictions on use

Recommended Use Buffer

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician	Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

None anticipated

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid creating or inhaling dust. Ensure adequate ventilation. Avoid contact with eyes, skin, or clothing. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from acids. Store in a dry location.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls	A well ventilated area to control dust levels. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment	If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection	Not normally needed. But if significant exposures are possible then the following respirator is recommended: Dust/mist respirator. (N95, P2/P3)
Hand Protection	Normal work gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid	**Color**	White
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	8
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.87
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Strong acids.

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact May cause mechanical irritation to eye.
Skin Contact None known.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 27-Sep-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-14004

Revision Date: 30-May-2017 **Revision Number:** 6

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-14004

Other means of Identification

Synonyms None

Hazardous Material Number: HM007652

Recommended use of the chemical and restrictions on use

Recommended Use Additive

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage/Irritation	Category 2 - H319

Label elements, including precautionary statements

Hazard Pictograms



Signal Word WARNING

Hazard Statements: H319 - Causes serious eye irritation

Precautionary Statements

Prevention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear eye protection/face protection

Response
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention

Storage None

Disposal None

Contains Substances	**CAS Number**
Sodium carbonate	497-19-8

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Sodium carbonate	497-19-8	60 - 100%	Eye Irrit. 2 (H319)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure
Causes eye irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from acids. Store in a cool, dry location. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Sodium carbonate	497-19-8	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Localized ventilation should be used to control dust levels.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection Dust/mist respirator. (N95, P2/P3)

Hand Protection Normal work gloves.

Skin Protection Normal work coveralls.

Eye Protection Dust proof goggles.

Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Powder
Color White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	11.4
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	2.5
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	105.99 g/mol
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong acids.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes eye irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium carbonate	497-19-8	4090 mg/kg (Rat) 2800 mg/kg (Rat)	2210 mg/kg (Mouse) > 2000 mg/kg (Rabbit)	2.3 mg/L (Rat) 2h

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact Causes eye irritation.
Skin Contact Not irritating to skin in rabbits.
Ingestion Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Sodium carbonate	497-19-8	Non-irritating to the skin

Substances	CAS Number	Serious eye damage/irritation
Sodium carbonate	497-19-8	Irritating to eyes

Substances	CAS Number	Skin Sensitization
Sodium carbonate	497-19-8	Not classified

Substances	CAS Number	Respiratory Sensitization
Sodium carbonate	497-19-8	No information available

Substances	CAS Number	Mutagenic Effects
Sodium carbonate	497-19-8	In vivo tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Sodium carbonate	497-19-8	No information available

Substances	CAS Number	Reproductive toxicity
Sodium carbonate	497-19-8	Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Sodium carbonate	497-19-8	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Sodium carbonate	497-19-8	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Sodium carbonate	497-19-8	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Sodium carbonate	497-19-8	EC50 242 mg/L (Nitzschia)	TLM24 385 mg/L (Lepomis macrochirus)	No information available	EC50 265 mg/L (Daphnia magna)

			LC50 310-1220 mg/L (Pimephales promelas) LC50 (96h) 300 mg/L (Lepomis macrochirus)		EC50 (48h) 200 – 227 mg/L (Ceriodaphnia sp.)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Sodium carbonate	497-19-8	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Sodium carbonate	497-19-8	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Sodium carbonate	497-19-8	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number Not restricted
UN proper shipping name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

IMDG/IMO

UN Number Not restricted
UN proper shipping name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

IATA/ICAO

UN Number Not restricted
UN proper shipping name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 30-May-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H319 - Causes serious eye irritation

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration

OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-16001

Revision Date: 05-Jul-2017 **Revision Number:** 11

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-16001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007655

Recommended use of the chemical and restrictions on use

Recommended Use Clay Stabilization Agent

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not classified

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician	Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Not applicable

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Not normally necessary.

Hand Protection Rubber gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	White
Odor:	Mild amine	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	7-9
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.07 - 1.091
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

Avoid contact with metals such as aluminum, tin, lead, brass, bronze, copper, and zinc.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Oxides of nitrogen. Hydrogen chloride. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Symptoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation None known.

Eye Contact None known.
Skin Contact None known.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability
Expected to be readily biodegradable

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects
Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-17001

Revision Date: 09-Nov-2017 **Revision Number:** 16

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-17001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007659

Recommended use of the chemical and restrictions on use

Recommended Use Corrosion Inhibitor

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Skin Sensitization	Category 1 - H317
Reproductive Toxicity	Category 1B - H360
Specific Target Organ Toxicity - (Single Exposure)	Category 1 - H370
Specific Target Organ Toxicity - (Repeated Exposure)	Category 2 - H373
Acute Aquatic Toxicity	Category 2 - H401
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H226 - Flammable liquid and vapor
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H360 - May damage fertility or the unborn child
H370 - Causes damage to organs
H373 - May cause damage to organs through prolonged or repeated exposure
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take action to prevent static discharges.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required

Response
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P307 + P311 - IF exposed: Call a POISON CENTER or doctor/physician
P314 - Get medical attention/advice if you feel unwell
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Diethylene glycol	111-46-6
Cinnamaldehyde	104-55-2
Amine oxides, cocoalkyldimethyl	61788-90-7
Methanol	67-56-1
Benzaldehyde	100-52-7
Alcohols, C12-16, ethoxylated	68551-12-2
Sodium iodide	7681-82-5

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	**CAS Number**	**PERCENT (w/w)**	**GHS Classification - Australia**
Diethylene glycol	111-46-6	30 - 60%	Acute Tox. 4 (H302) STOT RE 2 (H373)
Cinnamaldehyde	104-55-2	30 - 60%	Acute Tox. 4 (H312) Skin Irrit. 2 (H315) Skin Sens. 1 (H317) Aquatic Acute 2 (H401)
Amine oxides, cocoalkyldimethyl	61788-90-7	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400)
Methanol	67-56-1	10 - 30%	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Repr. 1B (H360) STOT SE 1 (H370) Flam. Liq. 2 (H225)
Benzaldehyde	100-52-7	5 - 10%	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Aquatic Acute 2 (H401) Flam. Liq. 4 (H227)
Alcohols, C12-16, ethoxylated	68551-12-2	1 - 5%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 3 (H412)
Sodium iodide	7681-82-5	1 - 5%	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) STOT SE 3 (H335) STOT RE 1 (H372)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Get immediate medical attention. Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. May cause allergic skin reaction. Harmful if swallowed. May cause damage to internal organs. May cause damage to organs through prolonged or repeated exposure. Potential reproductive hazard. May cause birth defects.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Carbon dioxide, dry chemical, foam.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May be ignited by heat, sparks or flames Use water spray to cool fire exposed surfaces. Closed containers may explode in fire. Decomposition in fire may produce harmful gases. Runoff to sewer may cause fire or explosion hazard.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove sources of ignition. Use appropriate protective equipment. Wear self-contained breathing apparatus in enclosed areas. Avoid breathing vapors. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Remove ignition sources and work with non-sparking tools. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Remove sources of ignition. Ensure adequate ventilation. Avoid breathing vapors. Avoid contact with eyes, skin, or clothing. Wash hands after use. Launder contaminated clothing before reuse. Ground and bond containers when transferring from one container to another. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Keep from heat, sparks, and open flames. Store in a well ventilated area. Store locked up. Keep container closed when not in use. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Diethylene glycol	111-46-6	TWA: 23 ppm TWA: 100 mg/m³	Not applicable
Cinnamaldehyde	104-55-2	Not applicable	Not applicable
Amine oxides, cocoalkyldimethyl	61788-90-7	Not applicable	Not applicable
Methanol	67-56-1	TWA: 200 ppm TWA: 262 mg/m³ STEL: 250 ppm STEL: 328 mg/m³	TWA: 200 ppm STEL: 250 ppm
Benzaldehyde	100-52-7	Not applicable	Not applicable
Alcohols, C12-16, ethoxylated	68551-12-2	Not applicable	Not applicable
Sodium iodide	7681-82-5	Not applicable	TWA: 0.01 ppm

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Positive pressure self-contained breathing apparatus if methanol is released.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Rubber apron.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Yellow-orange
Odor: Cinnamon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.85 (10%)
Freezing Point / Range	-21 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	28.9 °C / 84 °F PMCC
Evaporation rate	No data available

Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.015
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

Keep away from heat, sparks and flame.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Ammonia. Oxides of nitrogen. Hydrocarbons. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes skin irritation. May cause allergic skin reaction. Harmful if swallowed. May cause damage to internal organs. May cause damage to organs through prolonged or repeated exposure. Potential reproductive hazard. May cause birth defects.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diethylene glycol	111-46-6	12565 - 19600 mg/kg (Rat)	11890 - 13300 mg/kg (Rabbit)	> 4.6 mg/L (Rat) 4h
Cinnamaldehyde	104-55-2	2220 mg/kg (rat)	620 mg/kg (rabbit)	No data available
Amine oxides, cocoalkyldimethyl	61788-90-7	846 - 3873 mg/kg (Rat) 1000-1250 mg/kg (Rat)	4290 mg/kg (Rabbit)	No data available
Methanol	67-56-1	300 mg/kg-bw (human) < 790 to 13,000 mg/kg (rat)	1000 mg/kg-bw (human) 17,100 mg/kg (rabbit)	10 mg/L (human, 4h, vapor)
Benzaldehyde	100-52-7	1430 mg/kg (rat)	No information available	>1 <5 mg/L air (Rat, 4h, mist)
Alcohols, C12-16, ethoxylated	68551-12-2	1600 mg/kg	No data available	No data available
Sodium iodide	7681-82-5	4340 mg/kg (Rat) 3118 mg/kg (Rats) (Similar substance)	No data available	LCLo: 50000 mg/m³ (Mouse) 2h

Immediate, delayed and chronic health effects from exposure

Product Information Based on the collective toxicity of product ingredients, the mixture should be considered to cause the following:

Inhalation May cause respiratory irritation. May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.

Eye Contact Causes severe eye irritation which may damage tissue.

Skin Contact Causes skin irritation. May cause an allergic skin reaction.

Ingestion Harmful if swallowed. May cause central nervous system depression including headache, dizziness, drowsiness, muscular weakness, incoordination, slowed reaction time, fatigue blurred vision, slurred speech, giddiness, tremors and convulsions. May cause liver and kidney damage.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause reproductive system damage. Prolonged or repeated exposure may cause embryo and fetus toxicity.

Exposure Levels
No data available

Interactive effects
Skin disorders. Eye ailments.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Diethylene glycol	111-46-6	Non-irritating to the skin (Rabbit)
Cinnamaldehyde	104-55-2	Causes severe irritation and or burns (human)
Amine oxides, cocoalkyldimethyl	61788-90-7	Skin, rabbit: Causes moderate skin irritation.
Methanol	67-56-1	Non-irritating to the skin (Rabbit)
Benzaldehyde	100-52-7	Non-irritating to the skin (Rabbit)
Alcohols, C12-16, ethoxylated	68551-12-2	Causes skin irritation.
Sodium iodide	7681-82-5	Moderate dermal irritant (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Diethylene glycol	111-46-6	Non-irritating to the eye (Rabbit)
Cinnamaldehyde	104-55-2	Mild eye irritant. (human) (8 % solution)
Amine oxides, cocoalkyldimethyl	61788-90-7	Corrosive to eyes
Methanol	67-56-1	Non-irritating to the eye (Rabbit)
Benzaldehyde	100-52-7	Non-irritating to the eye (Rabbit)
Alcohols, C12-16, ethoxylated	68551-12-2	Causes severe eye irritation which may damage tissue.
Sodium iodide	7681-82-5	Moderately irritating to the eyes (Rabbit)

Substances	CAS Number	Skin Sensitization
Diethylene glycol	111-46-6	Did not cause sensitization on laboratory animals (guinea pig)
Cinnamaldehyde	104-55-2	Skin sensitizer in guinea pig.
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	Did not cause sensitization on laboratory animals (guinea pig)
Benzaldehyde	100-52-7	Not sensitizing in Guinea Pigs (Guinea Pig Maximisation Test and Open Epicutaneous Test, Sensitizing in Draize Test and Freund's Complete Adjuvant Test)
Alcohols, C12-16, ethoxylated	68551-12-2	Did not cause sensitization on laboratory animals
Sodium iodide	7681-82-5	Patch test on human volunteers did not demonstrate sensitization properties

Substances	CAS Number	Respiratory Sensitization
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No information available
Benzaldehyde	100-52-7	No information available
Alcohols, C12-16, ethoxylated	68551-12-2	No information available

Sodium iodide	7681-82-5	No information available

Substances	CAS Number	Mutagenic Effects
Diethylene glycol	111-46-6	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.
Cinnamaldehyde	104-55-2	In vitro tests did not show mutagenic effects.
Amine oxides, cocoalkyldimethyl	61788-90-7	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Methanol	67-56-1	The weight of evidence from available in vitro and in vivo studies indicates that this substance is not expected to be mutagenic.
Benzaldehyde	100-52-7	Not mutagenic in AMES Test. Negative in the chromosomal aberration assay In vitro tests have shown mutagenic effects In vivo tests did not show mutagenic effects.
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as mutagenic.
Sodium iodide	7681-82-5	In vitro tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Diethylene glycol	111-46-6	Did not show carcinogenic effects in animal experiments (Rat)
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No data of sufficient quality are available.
Benzaldehyde	100-52-7	Did not show carcinogenic effects in animal experiments (Rat) There was some evidence of carcinogenic activity in the forestomachs of mice.
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as carcinogenic.
Sodium iodide	7681-82-5	No information available

Substances	CAS Number	Reproductive toxicity
Diethylene glycol	111-46-6	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.
Cinnamaldehyde	104-55-2	Did not show teratogenic effects in animal experiments.
Amine oxides, cocoalkyldimethyl	61788-90-7	Did not show teratogenic effects in animal experiments. When tested at maternally toxic doses, no adverse effects on teratogenicity or development were observed.
Methanol	67-56-1	Experiments have shown reproductive toxicity effects on laboratory animals
Benzaldehyde	100-52-7	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Alcohols, C12-16, ethoxylated	68551-12-2	Not regarded as a reproductive and developmental toxicant.
Sodium iodide	7681-82-5	Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Diethylene glycol	111-46-6	No significant toxicity observed in animal studies at concentration requiring classification.
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	May cause respiratory irritation.
Methanol	67-56-1	May cause disorder and damage to the Central Nervous System (CNS)
Benzaldehyde	100-52-7	May cause respiratory irritation.
Alcohols, C12-16, ethoxylated	68551-12-2	No significant toxicity observed in animal studies at concentration requiring classification.
Sodium iodide	7681-82-5	No information available

Substances	CAS Number	STOT - repeated exposure
Diethylene glycol	111-46-6	Causes damage to organs through prolonged or repeated exposure: Kidney
Cinnamaldehyde	104-55-2	No significant toxicity observed in animal studies at concentration requiring classification.
Amine oxides, cocoalkyldimethyl	61788-90-7	No data of sufficient quality are available.
Methanol	67-56-1	No data of sufficient quality are available.
Benzaldehyde	100-52-7	No significant toxicity observed in animal studies at concentration requiring classification.
Alcohols, C12-16, ethoxylated	68551-12-2	No significant toxicity observed in animal studies at concentration requiring classification.
Sodium iodide	7681-82-5	Causes damage to organs through prolonged or repeated exposure: (Thyroid)

Substances	CAS Number	Aspiration hazard
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	Not applicable
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available

Methanol	67-56-1	Not applicable
Benzaldehyde	100-52-7	Not applicable
Alcohols, C12-16, ethoxylated	68551-12-2	Not applicable
Sodium iodide	7681-82-5	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Diethylene glycol	111-46-6	TGK (8d) 2700 mg/L (Scenedesmus quadricauda)	LC50 75200 mg/L (Pimephales promelas)	EC20 (30m) > 1995 mg/L (domestic activated sludge)	EC50 84000 mg/L (Daphnia magna) EC50 >10000 mg/L (Daphnia magna)
Cinnamaldehyde	104-55-2	EC50 (72 h) 2.1 mg/L (Skeletonema costatum)	LC50 (96 h) 2.38 mg/L (Scophthalmus maximus)	IC50 (48h) 131.2 mg/L (Tetrahymena pyriformis)	LC50 (48 h) 1.4 mg/L (Acartia tonsa)
Amine oxides, cocoalkyldimethyl	61788-90-7	ErC50 (72h) 0.29 mg/L (Selenastrum capricornutum) ErC50 (72h) 0.0235 mg/L (Scendesmus subspicatus) (similar substance)	LC50 (96h) 1.0–3.4 mg/L (Brachydanio rerio) LC50 (96h) 13.0 (Salmo gairdneri) LC50 (96h) 0.1-1 mg/L (Brachydanio rerio)	EC50 (3h) 240 mg/L (Pseudomonas putida) EC50 (3h) 13 mg/L (Activated sludge)	EC50 (48h) 2.9 mg/L (Daphnia magna) EC50 (48h) 0.083 mg/L (Daphnia magna) (similar substance)
Methanol	67-56-1	EC50 (96 h) =22000 mg/L (Pseudokirchnerella subcapitata) NOEC (8 d) =8000 mg/L (Scenedesmus quadricauda)	LC50 (96 h) =15400 mg/L (Lepomis macrochirus) EC50 (200 h) =14536 mg/L (Oryzias latipes)	IC50 (3h) > 1000 mg/L (activated sludge)	EC50 (96 h) =18260 mg/L (Dapnia magna) NOEC (21 d) =208 mg/L (Dapnia magna)
Benzaldehyde	100-52-7	NOEC (8d) 20 mg/L (Microcystis aeruginosa) NOEC (8d) 132 mg/L	LC50 (96 h) 1.07 mg/L (Lepomis macrochirus)	IC50 (3 h) 740 mg/L (Activated sludge)	EC50 (24 h) 50 mg/L (Daphnia magna)
Alcohols, C12-16, ethoxylated	68551-12-2	EC50 0.7 mg/L (Selenastrum capricornutum)	No information available	No information available	0.39 mg/L (Daphnia Magna)
Sodium iodide	7681-82-5	7 d Tox threshold: 2370 mg/L (Scenedesmus quadricauda, biomass) EC50(72h): 2588.7 mg/L (Skeletonema costatum)	LC50(96h): 3780 mg/L (Oncorhynchus mykiss) LC50(96h): > 100 mg/L (Scopthalmus maximus)	No information available	EC50(48h): 1.27 mg/L (Daphnia magna) EC50(48h): 575 mg/L (Acartia tonsa)

12.2. Persistence and degradability

No data is available on the product itself

Substances	CAS Number	Persistence and Degradability
Diethylene glycol	111-46-6	Readily biodegradable (90-100% @ 28d)
Cinnamaldehyde	104-55-2	Predicted to be readily biodegradable.
Amine oxides, cocoalkyldimethyl	61788-90-7	Readily biodegradable (81% @ 28d)
Methanol	67-56-1	Readily biodegradable (95% @ 20d)
Benzaldehyde	100-52-7	Readily biodegradable (>=95% @ 28d)
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	Not applicable

12.3. Bioaccumulative potential

No data is available on the product itself

Substances	CAS Number	Log Pow
Diethylene glycol	111-46-6	BCF: 100 (Leuciscus idus melanotus)
Cinnamaldehyde	104-55-2	Log Pow =1.4
Amine oxides, cocoalkyldimethyl	61788-90-7	Log Kow = 7.5
Methanol	67-56-1	Not Bioaccumulative; BCF=1
Benzaldehyde	100-52-7	Log Pow =1.1
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	-1.301

12.4. Mobility in soil

Substances	CAS Number	Mobility
Diethylene glycol	111-46-6	No information available
Cinnamaldehyde	104-55-2	No information available
Amine oxides, cocoalkyldimethyl	61788-90-7	No information available
Methanol	67-56-1	No information available
Benzaldehyde	100-52-7	No information available
Alcohols, C12-16, ethoxylated	68551-12-2	No information available
Sodium iodide	7681-82-5	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Incineration recommended in approved incinerator according to federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging
Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable
EMS: EmS F-E, S-E

IATA/ICAO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Methanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
•3Y

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 09-Nov-2017

Revision Note

SDS sections updated:
14

Full text of H-Statements referred to under sections 2 and 3

H225 - Highly flammable liquid and vapor
H226 - Flammable liquid and vapor
H227 - Combustible liquid
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H311 - Toxic in contact with skin
H312 - Harmful in contact with skin
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H331 - Toxic if inhaled
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H370 - Causes damage to organs
H372 - Causes damage to organs through prolonged or repeated exposure
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
NZ CCID

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-17003

Revision Date: 30-Apr-2019 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-17003

Other means of Identification

Synonyms None

Hazardous Material Number: HM007699

Recommended use of the chemical and restrictions on use

Recommended Use Inhibitor

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute toxicity - Dermal	Category 3 - H311
Serious Eye Damage/Irritation	Category 2 - H319
Germ Cell Mutagenicity	Category 2 - H341
Carcinogenicity	Category 2 - H351
Specific Target Organ Toxicity - (Repeated Exposure)	Category 2 - H373
Acute Aquatic Toxicity	Category 3 - H402
Flammable liquids.	Category 2 - H225

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H225 - Highly flammable liquid and vapor
H311 - Toxic in contact with skin
H319 - Causes serious eye irritation
H341 - Suspected of causing genetic defects
H351 - Suspected of causing cancer
H373 - May cause damage to organs through prolonged or repeated exposure
H402 - Harmful to aquatic life

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take action to prevent static discharges.
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/eye protection/face protection
P281 - Use personal protective equipment as required

Response
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P312 - Call a POISON CENTER/doctor/physician if you feel unwell
P361 - Take off immediately all contaminated clothing.
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P314 - Get medical attention/advice if you feel unwell
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Aldol	107-89-1
Crotonaldehyde	123-73-9
Acetaldehyde	75-07-0

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Aldol	107-89-1	30 - 60%	Acute Tox. 2 (H310) Eye Irrit. 2A (H319) Flam. Liq. 4 (H227)
Crotonaldehyde	123-73-9	1 - 5%	Acute Tox. 3 (H301) Acute Tox. 2 (H310) Acute Tox. 2 (H330) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Muta. 2 (H341) STOT SE 3 (H335) STOT RE 1 (H372) Aquatic Acute 1 (H400) Flam. Liq. 2 (H225)
Acetaldehyde	75-07-0	1 - 5%	Acute Tox. 4 (H302) Acute Tox. 4 (H332) Eye Irrit. 2 (H319) Muta. 2 (H341) Carc. 2 (H351) STOT SE 3 (H335) Aquatic Acute 3 (H402) Flam. Liq. 1 (H224)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes eye irritation. Toxic in contact with skin. May cause heritable genetic damage. Potential carcinogen. May cause damage to organs through prolonged or repeated exposure.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May be ignited by heat, sparks or flames Use water spray to cool fire exposed surfaces. Closed containers may explode in fire. Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove sources of ignition. Use appropriate protective equipment. Wear self-contained breathing apparatus in enclosed areas. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Remove ignition sources and work with non-sparking tools. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Use appropriate protective equipment. Remove sources of ignition. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Ground and bond containers when transferring from one container to another.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Keep from heat, sparks, and open flames. Keep container closed when not in use. Product has a shelf life of 36 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Aldol	107-89-1	Not applicable	Not applicable
Crotonaldehyde	123-73-9	Not applicable	Not applicable
Acetaldehyde	75-07-0	TWA: 20 ppm TWA: 36 mg/m^3 STEL: 50 ppm STEL: 91 mg/m^3	Ceiling: 25 ppm

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this

product.

Respiratory Protection	Organic vapor respirator.
Hand Protection	Impervious rubber gloves.
Skin Protection	Rubber apron.
Eye Protection	Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear colorless to pale yellow
Odor:	Pungent	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	5-7
Freezing Point / Range	-30 °C
Melting Point / Range	No data available
Pour Point / Range	No data available
Boiling Point / Range	100 °C / 212 °F
Flash Point	18 °C / 65 °F (PMCC)
Evaporation rate	No data available
Vapor Pressure	0.1
Vapor Density	3.04
Specific Gravity	1.053
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers. Strong alkalis. Strong acids.
10.6. Hazardous decomposition products
Oxides of nitrogen. Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure	Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes eye irritation. Toxic in contact with skin. May cause heritable genetic damage. Potential carcinogen. May cause damage to organs through prolonged or repeated exposure.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Aldol	107-89-1	2180 mg/kg (Rat)	140 mg/kg (Rabbit)	No data available
Crotonaldehyde	123-73-9	206 mg/kg-bw (rat)	128 mg/kg-bw (rabbit)	0.2 mg/L (rat, 4h, assuming mist)
Acetaldehyde	75-07-0	660 mg/kg bw (rat)	No information available	13 mg/L (rat, vapor, 4 hr)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause respiratory irritation.

Eye Contact Causes eye irritation.

Skin Contact Toxic in contact with skin. May cause skin defatting with prolonged exposure.

Ingestion Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity This product contains a potential carcinogen. May cause heritable genetic damage. Prolonged or repeated exposure may cause liver damage.

Exposure Levels

No data available

Interactive effects

Skin disorders. Eye ailments.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Aldol	107-89-1	May cause mild skin irritation. (Rabbit)
Crotonaldehyde	123-73-9	Causes moderate skin irritation. (Rabbit) Causes skin irritation. Skin, rabbit:
Acetaldehyde	75-07-0	Non-irritating to the skin (Rabbit) Not irritating to skin in rabbits.

Substances	CAS Number	Serious eye damage/irritation
Aldol	107-89-1	Causes moderate eye irritation (Rabbit)
Crotonaldehyde	123-73-9	Causes severe eye irritation which may damage tissue. (Rabbit) Eye, rabbit: Causes severe eye irritation
Acetaldehyde	75-07-0	Causes moderate eye irritation (Rabbit) Eye, rabbit:

Substances	CAS Number	Skin Sensitization
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	Not regarded as a sensitizer. No data of sufficient quality are available.
Acetaldehyde	75-07-0	Did not cause sensitization on laboratory animals (guinea pig) Patch test on human volunteers did not demonstrate sensitization properties

Substances	CAS Number	Respiratory Sensitization
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	No information available
Acetaldehyde	75-07-0	No information available

Substances	CAS Number	Mutagenic Effects
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	Some in vivo tests have shown mutagenic effects.
Acetaldehyde	75-07-0	Some in vitro tests have shown mutagenic effects. Some in vivo tests have shown mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	No data of sufficient quality are available. Substances which cause concern for man owing to possible carcinogenic effects but for which the available information is not adequate for making a satisfactory assessment
Acetaldehyde	75-07-0	This substance is a potential carcinogen. Substances which should be regarded as if they are

		carcinogenic to man

Substances	CAS Number	Reproductive toxicity
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	No data of sufficient quality are available.
Acetaldehyde	75-07-0	No data of sufficient quality are available.

Substances	CAS Number	STOT - single exposure
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	May cause respiratory irritation.
Acetaldehyde	75-07-0	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	Causes damage to organs through prolonged or repeated exposure if swallowed: (Liver)
Acetaldehyde	75-07-0	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	No information available
Acetaldehyde	75-07-0	No information available Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Aldol	107-89-1	EC50 (5d) >237 mg/L (Nitzscheria linearis)	No information available	No information available	No information available
Crotonaldehyde	123-73-9	EC50 (96h) 0.881 mg/L	LC50 (96 h) =0.71 mg/L (Trout) LOEC (NR) =0.22 mg/L (Fathead minnow)	No information available	EC50 (28 d) >1.5 mg/L (Daphnia magna)
Acetaldehyde	75-07-0	EC50 (5 d) >237 mg/L (Nitzscheria linearis)	LC50 (96 h) =30.8 mg/L (Pimephales promelas)	No information available	EC50 (48 h) =48.25 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	(55% @ 28d)
Acetaldehyde	75-07-0	Readily biodegradable (80% @ 14d)

12.3. Bioaccumulative potential

Substances	CAS Number	Bioaccumulation
Aldol	107-89-1	-0.72
Crotonaldehyde	123-73-9	Log Kow =0.68
Acetaldehyde	75-07-0	Log Pow =0.63

12.4. Mobility in soil

Substances	CAS Number	Mobility
Aldol	107-89-1	No information available
Crotonaldehyde	123-73-9	No information available
Acetaldehyde	75-07-0	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	UN1992
UN proper shipping name:	Flammable Liquid, Toxic, N.O.S. (Contains Acetaldehyde, Aldol)
Transport Hazard Class(es):	3 (6.1)
Packing Group:	II
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	UN1992
UN proper shipping name:	Flammable Liquid, Toxic, N.O.S. (Contains Acetaldehyde, Aldol)
Transport Hazard Class(es):	3 (6.1)
Packing Group:	II
Environmental Hazards:	Not applicable
EMS:	EmS F-E, S-D

IATA/ICAO

UN Number	UN1992
UN proper shipping name:	Flammable Liquid, Toxic, N.O.S. (Contains Acetaldehyde, Aldol)
Transport Hazard Class(es):	3 (6.1)
Packing Group:	II
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
2WE

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances: Does not apply.

Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 30-Apr-2019

Revision Note

Full text of H-Statements referred to under sections 2 and 3
H224 - Extremely flammable liquid and vapor
H225 - Highly flammable liquid and vapor
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H310 - Fatal in contact with skin
H311 - Toxic in contact with skin
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H330 - Fatal if inhaled
H332 - Harmful if inhaled
H335 - May cause respiratory irritation
H341 - Suspected of causing genetic defects
H351 - Suspected of causing cancer
H372 - Causes damage to organs through prolonged or repeated exposure if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-18003

Revision Date: 10-May-2016 **Revision Number:** 3

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-18003

Other means of Identification

Synonyms None

Hazardous Material Number: HM007695

Recommended use of the chemical and restrictions on use

Recommended Use Corrosion Inhibitor; Intensifier

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Substances/mixtures corrosive to metal. Flammable liquids.	Category 1 Category 4 - H227
Substances/mixtures corrosive to metal	Category 1 - H290

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H227 - Combustible liquid
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage

Precautionary Statements

Prevention
P103 - Read label before use
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P234 - Keep only in original container
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P370 + P378 - In case of fire: Use water spray for extinction
P390 - Absorb spillage to prevent material damage

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up
P406 - Store in corrosive resistant container with a resistant inner liner.

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Glycol ether	Proprietary
Hydrochloric acid	7647-01-0

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Glycol ether	Proprietary	10 - 30%	Eye Irrit. 2A (H319) Flam. Liq. 3 (H226)
Hydrochloric acid	7647-01-0	10 - 30%	Skin Corr. 1B (H314) Eye Corr. 1 (H318) STOT SE 3 (H335)

			Met. Corr. 1 (H290)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May form explosive mixtures with strong alkalis. Decomposition in fire may produce harmful gases. Reaction with steel and certain other metals generates flammable hydrogen gas. Do not allow runoff to enter waterways. Vapors are heavier than air and may accumulate in low areas. Vapors may travel along the ground to be ignited at distant locations.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Isolate area and remove sources of friction, impact, heat, low level electrical current, and RF energy. Contain spill with sand or other inert materials. Remove ignition sources and work with non-sparking tools. Neutralize to pH of 6-8. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Wash hands after use. Launder contaminated clothing before reuse.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from alkalis. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Glycol ether	Proprietary	Not applicable	Not applicable
Hydrochloric acid	7647-01-0	5 ppm	TWA: 2 ppm (Ceiling)

Appropriate engineering controls

Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection Organic vapor/acid gas respirator.

Hand Protection Impervious rubber gloves.

Skin Protection Full protective chemical resistant clothing. Rubber boots

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid **Color** Clear colorless to pale yellow

Odor: Odorless **Odor Threshold:** No information available

Property Remarks/ - Method	Values
pH:	0.61 (10%)
Freezing Point / Range	-27 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	63.3 °C / 146 °F PMCC
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.372
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong alkalis.
10.6. Hazardous decomposition products
Flammable hydrogen gas. Chlorine. Hydrogen sulfide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Glycol ether	Proprietary	No data available	3550 mg/kg (Rabbit) 4 mL/kg (Rabbit)	No data available
Hydrochloric acid	7647-01-0	No data available	5010 mg/kg (Rabbit) > 5010 mg/kg (Rabbit) 1449 mg/kg (Mouse)	3124 mg/L (Rat) 1h 3.2 mg/L (Mouse) 8.3 mg/L (Rat) 1405 mg/L (Rat) 554 mg/L (Mouse)

Immediate, delayed and chronic health effects from exposure
Inhalation May cause respiratory irritation.
Eye Contact Causes severe eye irritation which may damage tissue.
Skin Contact Causes severe skin irritation with tissue destruction.
Ingestion Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Glycol ether	Proprietary	Not irritating to skin in rabbits.
Hydrochloric acid	7647-01-0	Causes severe burns

Substances	CAS Number	Serious eye damage/irritation
Glycol ether	Proprietary	Causes moderate eye irritation (Rabbit)

Hydrochloric acid	7647-01-0	Causes severe burns

Substances	CAS Number	Skin Sensitization
Glycol ether	Proprietary	Did not cause sensitization on laboratory animals
Hydrochloric acid	7647-01-0	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Glycol ether	Proprietary	No information available
Hydrochloric acid	7647-01-0	No information available

Substances	CAS Number	Mutagenic Effects
Glycol ether	Proprietary	In vitro tests did not show mutagenic effects.
Hydrochloric acid	7647-01-0	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Glycol ether	Proprietary	No information available
Hydrochloric acid	7647-01-0	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Glycol ether	Proprietary	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Hydrochloric acid	7647-01-0	Embryo and fetotoxicity has been observed in female rats exposed to maternally toxic levels of hydrogen chloride (450 mg/m^3, 1hr.).

Substances	CAS Number	STOT - single exposure
Glycol ether	Proprietary	No significant toxicity observed in animal studies at concentration requiring classification.
Hydrochloric acid	7647-01-0	May cause respiratory irritation.

Substances	CAS Number	STOT - repeated exposure
Glycol ether	Proprietary	No significant toxicity observed in animal studies at concentration requiring classification.
Hydrochloric acid	7647-01-0	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Glycol ether	Proprietary	Not applicable
Hydrochloric acid	7647-01-0	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Glycol ether	Proprietary	EC50 (96h) 1466 mg/L (cell number) (Pseudokirchnerella subcapitata) EC50 (48h) 3440 mg/L (Pseudokirchnerella subcapitata)	LC50 (96h) 3,400 mg/L (Pimephales promelas) LC50 (96h) > 100 mg/L (Oncorhynchus mykiss)	EC50 (16h) 3800 mg/L (Bacteria)	LC50 3,600 mg/L EC50 (48h) > 100 mg/L (Daphnia magna)
Hydrochloric acid	7647-01-0	No information available	LC50 282 mg/L (Gambusia affinis) LC50 20.5 mg/L (Lepomis macrochirus) LC50 (96h) 3.25 – 3.5 (pH) (Lepomis macrochirus)	EC50 (3h) >= 5 and <= 5.5 (pH) (Activated sludge, domestic)	EC50 (48h) 4.9 (pH) (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Glycol ether	Proprietary	Readily biodegradable (91.5% @ 28d)

Hydrochloric acid	7647-01-0	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Glycol ether	Proprietary	0.621
Hydrochloric acid	7647-01-0	0.25

12.4. Mobility in soil

Substances	CAS Number	Mobility
Glycol ether	Proprietary	No information available
Hydrochloric acid	7647-01-0	No information available

12.6. Other adverse effects

Endocrine Disruptor Information
This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods
Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging
Follow all applicable national or local regulations.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number UN1789
UN proper shipping name: Hydrochloric Acid Solution
Transport Hazard Class(es): 8
Packing Group: II
Environmental Hazards: Not applicable

Special precautions during transport
None

HazChem Code
2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
S6

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 10-May-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
H226 - Flammable liquid and vapor
H227 - Combustible liquid
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement
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conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-23001

Revision Date: 30-Sep-2015 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-23001

Other means of Identification

Synonyms: None

Product Code: HM007701

Recommended use of the chemical and restrictions on use

Recommended Use Friction Reducer

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical
Special Exposure Hazards
Not applicable.

Special protective equipment and precautions for fire fighters
Special Protective Equipment for Fire-Fighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Ground and bond containers when transferring from one container to another. Slippery when wet. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use. Keep from heat, sparks, and open flames. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection Normal work gloves.
Skin Protection Normal work coveralls.

Eye Protection	Wear safety glasses or goggles to protect against exposure.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Powder	**Color:**	White
Odor:	Slight	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	9
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	2
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical Stability

Stable

10.3. Possibility of Hazardous Reactions

Will Not Occur

10.4. Conditions to Avoid

None anticipated

10.5. Incompatible Materials

Strong oxidizers.

10.6. Hazardous Decomposition Products

Carbon monoxide and carbon dioxide. Ammonia.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure

Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion Large doses may cause nausea, vomiting and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Respiratory disorders. Skin disorders.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-23003

Revision Date: 31-Jul-2018 **Revision Number:** 8

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-23003

Other means of Identification

Synonyms None

Hazardous Material Number: HM008080

Recommended use of the chemical and restrictions on use

Recommended Use Friction Reducer

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Hydrotreated light petroleum distillate	64742-47-8
Ethoxylated branched C13 alcohol	78330-21-9
Sodium diacetate	126-96-5

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrotreated light petroleum distillate	64742-47-8	10 - 30%	Asp. Tox. 1 (H304)
Ethoxylated branched C13 alcohol	78330-21-9	1 - 5%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 3 (H412)
Sodium diacetate	126-96-5	1 - 5%	Eye Corr. 1 (H318)

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, move victim to fresh air and seek medical attention.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists. Remove contaminated clothing and launder before reuse.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire
Product is not expected to burn unless all the water is boiled away. Decomposition in fire may produce harmful gases. Use water spray to cool fire exposed surfaces.

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Spills of this product are very slippery. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions
Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove. Do NOT spread spilled product with water.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Use appropriate protective equipment. Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Avoid breathing mist. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use. Store at temperatures between 40 and 90 F (5 and 35 C). Keep from freezing. Product has a shelf life of 6 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrotreated light petroleum distillate	64742-47-8	Not applicable	Not applicable
Ethoxylated branched C13 alcohol	78330-21-9	Not applicable	Not applicable
Sodium diacetate	126-96-5	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator is recommended:
Organic vapor respirator with a dust/mist filter. (A2P2/P3)
Hand Protection Impervious rubber gloves. Polyvinylchloride gloves.
Skin Protection Normal work coveralls.
Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Off white
Odor: Hydrocarbon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	5 - 8
Freezing Point / Range	No data available
Melting Point / Range	< 5 °C / < 41 °F
Boiling Point / Range	> 100 °C / 212 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	17.25 mmHg
Vapor Density	No data available
Specific Gravity	1.0 - 1.1
Water Solubility	Miscible with water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	> 20.5 mm2/s
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Freezing conditions.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide. Oxides of nitrogen. Hydrogen cyanide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrotreated light	64742-47-8	>5000 mg/kg-bw (rat) (similar	>2000 mg/kg-bw (rabbit) (similar	>5.2 mg/L (rat, 4 h, vapor)

petroleum distillate		substance)	substance)	(similar substance)
Ethoxylated branched C13 alcohol	78330-21-9	1600 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rabbit) (similar substance)	>0.22 mg/L (rat, 4h, aerosol, saturated) (similar substance)
Sodium diacetate	126-96-5	5600 mg/kg (rat)	> 2000 mg/kg (rat)	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation If heated: May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.

Eye Contact In vitro tests indicate that the product is not an eye irritant.

Skin Contact Prolonged or repeated contact may cause skin irritation.

Ingestion May act as obstruction if swallowed. Aspiration can be a hazard if this material is swallowed.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Eye ailments. Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to the skin (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Skin, rabbit: Causes moderate skin irritation. (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to rabbit's eye (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Eye, rabbit: Causes severe eye irritation which may damage tissue. (similar substances)

Substances	CAS Number	Skin Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Sodium diacetate	126-96-5	Not regarded as a sensitizer.

Substances	CAS Number	Respiratory Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Based on available data, the classification criteria are not met.
Ethoxylated branched C13 alcohol	78330-21-9	Based on available data, the classification criteria are not met.
Sodium diacetate	126-96-5	No information available

Substances	CAS Number	Mutagenic Effects
Hydrotreated light petroleum distillate	64742-47-8	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Hydrotreated light petroleum distillate	64742-47-8	Did not show carcinogenic effects in animal experiments (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Did not show carcinogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Hydrotreated light petroleum distillate	64742-47-8	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Sodium diacetate	126-96-5	(similar substances)

Substances	CAS Number	STOT - single exposure
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification.
Ethoxylated branched C13 alcohol	78330-21-9	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Sodium diacetate	126-96-5	No information available

Substances	CAS Number	STOT - repeated exposure
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Ethoxylated branched C13 alcohol	78330-21-9	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Hydrotreated light petroleum distillate	64742-47-8	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Ethoxylated branched C13 alcohol	78330-21-9	Based on available data, the classification criteria are not met.

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrotreated light petroleum distillate	64742-47-8	ErL50(72 h)>10000 mg/L (Skeletonema costatum)	LC50(96 h)>10000 mg/L (Scophthalmus maximus) NOELR(28 d)>1000 mg/L (fish)	No information available	LC50(48 h)>10000 mg/L (Acartia tonsa) NOELR(21 d)=1000 mg/L (Daphnia magna)
Ethoxylated branched C13 alcohol	78330-21-9	IC50(72 h)=1-10 mg/L (Desmodesmus subspicatus)	LC50(96 h)=1-10 mg/L (Cyprinus carpio)	No information available	EC50(48 h)=1-10 mg/L (Daphnia magna) NOAEC (21d) 0.77 mg/L (Daphnia magna)
Sodium diacetate	126-96-5	EC50 (72 h) >1000 mg/L (Skeletonema costatum)	LC0 (96 h) >100 mg/L (Danio rerio) LC50 (96 h) 273 mg/L (Oreochromis mossambicus)	No information available	EC50 (48 h) >1000 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Hydrotreated light petroleum distillate	64742-47-8	Readily biodegradable (68.1% @ 28d)
Ethoxylated branched C13 alcohol	78330-21-9	Readily biodegradable (> 60% @ 28d)
Sodium diacetate	126-96-5	No information available

12.3. Bioaccumulative potential

Bioaccumulation is unlikely

Substances	CAS Number	Log Pow
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethoxylated branched C13 alcohol	78330-21-9	Not Bioaccumulative; BCF = 12.7 - 237 L/Kg
Sodium diacetate	126-96-5	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility

Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethoxylated branched C13 alcohol	78330-21-9	No information available
Sodium diacetate	126-96-5	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS

US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 31-Jul-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed
H304 - May be fatal if swallowed and enters airways
H315 - Causes skin irritation
H318 - Causes serious eye damage
H412 - Harmful to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
OSHA

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-23005

Revision Date: 09-Apr-2019 **Revision Number:** 1

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-23005

Other means of Identification

Synonyms None

Hazardous Material Number: HM009078

Recommended use of the chemical and restrictions on use

Recommended Use Friction Reducer

Uses advised against Consumer use

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention	None
Response	None
Storage	None
Disposal	None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not classified

The exact percentage (concentration) of the composition has been withheld as proprietary. The specific chemical identity of the composition has been withheld as proprietary.

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Rinse mouth with water many times. Get medical attention, if symptoms occur

Symptoms caused by exposure
No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water spray, dry chemical, or foam.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical
Special exposure hazards in a fire
Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Ensure adequate ventilation. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Slippery when wet. Take precautionary measures against static discharges

6.2. Environmental precautions
None known.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Use appropriate protective equipment. Ensure adequate ventilation. Avoid dust accumulations. Avoid contact with eyes, skin, or clothing. Slippery when wet.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Use good housekeeping in storage and work areas to prevent accumulation of dust. Close container when not in use. Avoid contact with heat, sparks, open flame, and static discharge. Store away from oxidizers. Store in a dry location. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls Ensure adequate ventilation, especially in confined areas

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)
Hand Protection Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.
Skin Protection Wear protective clothing appropriate for the work environment.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Powder
Color White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6 - 8 (1 % solution)
Freezing Point / Range	No data available
Melting Point / Range	No data available
Pour Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	> 100 °C / > 212 °F (Closed cup)
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.02
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available
Bulk Density	0.45 - 0.7 g/cm3

10. Stability and Reactivity

10.1. Reactivity
May form combustible dust concentrations in air.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Oxides of nitrogen. Carbon oxides. Hydrogen cyanide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation. Ingestion.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mechanical irritation to eye.
Skin Contact May cause mild skin irritation.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
No data available

Data limitations
No data available

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Bioaccumulation
Contains no hazardous substances in concentrations above cut-off values according to	NA	No information available

the competent authority		

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Follow all applicable community, national or regional regulations regarding waste management methods.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or

	assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 09-Apr-2019

Revision Note
Initial Release

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-25003

Revision Date: 30-Sep-2015 **Revision Number:** 13

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-25003

Other means of Identification

Synonyms: None

Product Code: HM007670

Recommended use of the chemical and restrictions on use

Recommended Use Gelling Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

Dust can form an explosive mixture in air
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid creating or inhaling dust. Avoid contact with eyes, skin, or clothing. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Normal work gloves.

Skin Protection Normal work coveralls.

Eye Protection Wear safety glasses or goggles to protect against exposure.

Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: White to light straw
Odor: Bean
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	10.1
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.3
Water Solubility	Hydrolyzes
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	510 °C / 950 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
Strong oxidizers.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Follow all applicable community, national or regional regulations regarding waste management methods.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number:	Not restricted
UN Proper Shipping Name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-25005

Revision Date: 30-Sep-2015 **Revision Number:** 10

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-25005

Other means of Identification

Synonyms: None

Product Code: HM007672

Recommended use of the chemical and restrictions on use

Recommended Use Gelling Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None

Response None

Storage None

Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Under normal conditions, first aid procedures are not required.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases. Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator is recommended:
Dust/mist respirator. (N95, P2/P3)

Hand Protection Normal work gloves.

Skin Protection Normal work coveralls.

Eye Protection Wear safety glasses or goggles to protect against exposure.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: Off white
Odor: Bean
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.5-7.5
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	> 93 °C / > 200 °F Cleveland Open Cup (COC)
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.42 - 1.47
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
Strong oxidizers.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above	NA	No data available	No data available	No data available

cut-off values according to the competent authority				

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact None known.
Ingestion None known.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 30-Sep-2015

Revision Note

SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-30001

Revision Date: 05-Jul-2016 **Revision Number:** 11

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-30001

Other means of Identification

Synonyms None

Hazardous Material Number: HM007676

Recommended use of the chemical and restrictions on use

Recommended Use Scale Inhibitor

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton/Baroid Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: 61 (08) 9455 8300
Fax Number: 61 (08) 9455 5300

Product Emergency Telephone
Australia: + 61 1 800 686 951
Papua New Guinea: + 61 1 800 686 951
NewZealand: +64 800 451719

Fire, Police & Ambulance - Emergency Telephone
Australia: 000
Papua New Guinea: 000
New Zealand: 111

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard pictograms

Signal Word Not Hazardous

Hazard Statements: Not Classified

Precautionary Statements

Prevention None
Response None
Storage None
Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Not applicable

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing mist. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Product has a shelf life of 12 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN

149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection	Butyl rubber gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear to slightly hazy amber
Odor:	Mild	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	6.49 - 7.49
Freezing Point / Range	-1.1 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C
Flash Point	> 95 °C / PMCC
Evaporation rate	< 1
Vapor Pressure	18 mmHg
Vapor Density	> 1
Specific Gravity	1.24
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	1.2
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide. Toxic monomer fumes.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye and skin contact.

Symptoms related to exposure
Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact Prolonged or repeated contact may cause slight skin irritation.
Ingestion In large amounts: Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
Skin disorders. Eye ailments. Respiratory disorders.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability
Biodegradable.

Substances	CAS Number	Persistence and Degradability

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 05-Jul-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
None

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour

mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

Disclaimer Statement
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-32002

Revision Date: 07-Feb-2018 **Revision Number:** 19

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-32002

Other means of Identification

Synonyms None

Hazardous Material Number: HM007683

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute Oral Toxicity	Category 4 - H302
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 2 - H401

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H302 - Harmful if swallowed
H315 - Causes skin irritation
H318 - Causes serious eye damage
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P273 - Avoid release to the environment
P280 - Wear protective gloves/eye protection/face protection

Response
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P330 - Rinse mouth
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician

Storage None

Disposal P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1

Other hazards which do not result in classification
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	60 - 100%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401)

4. First aid measures

Description of necessary first aid measures

Inhalation	Under normal conditions, first aid procedures are not required.
Eyes	Immediately flush eyes with large amounts of water for at least 15 minutes. Get immediate medical attention.
Skin	Wash with soap and water. Get medical attention if irritation persists.
Ingestion	Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. Harmful if swallowed.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Wash hands after use. Avoid breathing vapors. Ensure adequate ventilation. Slippery when wet. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Keep container closed when not in use. Keep from heat, sparks, and open flames. Product has a shelf life of 24 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Not applicable	Not applicable
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls None known.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.

Hand Protection Impervious rubber gloves. Polyvinylchloride gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Odor: Mild
Color Yellow
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	6.5 (1%)
Freezing Point / Range	-3 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	240 °C / 464 °F PMCC
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	> 10
Specific Gravity	0.98
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability

Stable

10.3. Possibility of hazardous reactions

Will Not Occur

10.4. Conditions to avoid

None anticipated

10.5. Incompatible materials

Strong oxidizers. Strong acids. Strong alkalis.

10.6. Hazardous decomposition products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue. Causes skin irritation. Harmful if swallowed.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	600 mg/kg (Rat) (similar substance)	> 5200 mg/kg (Rabbit) (similar substance)	> 0.22 mg/L (saturated concentration) (Rat) (similar substance)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	600 mg/kg (Rat) (similar substance)	> 5200 mg/kg (Rabbit) (similar substance)	>0.22 mg/L (saturated concentration) (Rat) (similar substance)

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue.

Skin Contact Causes skin irritation.

Ingestion Harmful if swallowed. Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

Skin disorders.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Causes skin irritation. (Rabbit) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Causes skin irritation. (Rabbit) (similar substances)

Substances	CAS Number	Serious eye damage/irritation
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Causes severe eye irritation (Rabbit) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Causes severe eye irritation (Rabbit) (similar substances)

Substances	CAS Number	Skin Sensitization

Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)

Substances	CAS Number	Respiratory Sensitization
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No information available
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No information available

Substances	CAS Number	Mutagenic Effects
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)

Substances	CAS Number	Carcinogenic Effects
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Did not show carcinogenic effects in animal experiments (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Did not show carcinogenic or teratogenic effects in animal experiments (similar substances)

Substances	CAS Number	Reproductive toxicity
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Animal testing did not show any effects on fertility.
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Animal testing did not show any effects on fertility.

Substances	CAS Number	STOT - single exposure
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	STOT - repeated exposure
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)

Substances	CAS Number	Aspiration hazard
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	No adverse health effects are expected from swallowing.
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	No adverse health effects are expected from swallowing.

12. Ecological Information

Ecotoxicity

Algae Toxicity ErC50 (72h): 2.58 - 3.44 mg/L (Desmodesmus subspicatus)

Acute Crustaceans Toxicity: EC50(48h): 1.45 - 1.79 mg/L (Daphnia magna)

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	EC50 (72h) 0.75 mg/L (Pseudokirchnerella subcapitata) (similar substance) EC50 (96h) 0.7 mg/L (Pseudokirchneriella subapitata) (similar substance) CD10 8 mg/L	LC50 (96h) 0.59 mg/L (Pleuronectes platessa) (similar substance) LC50 (96) 1.4 mg/L (Pimephales promelas) (similar substance) NOEC 4.4 mg/L (Pimephales promelas, juvenile)	ErC50 (16.9h) > 10 g/L (growth inhibition) (Pseudomonas putida) (similar substance)	EC50 (48h) 0.14 mg/L (Daphnia magna) (similar substance) EC50 (48h) 0.39 mg/L (Cerodaphnia dubia) (similar substance)

		(Pseudokirchneriella subapitata) EC10 2 mg/L (Brachionus calyciflorus)			
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	EC50 (72h) 0.75 mg/L (Pseudokirchnerella subcapitata) (similar substance) ErC50 (48h) 0.7 mg/L (Skeletonema costatum) EC10 9.79 mg/L (Selenastrum capricornutum) (similar substance) ErC50 1.1 mg/L (Scenedesmus subspicatus) (similar substance)	LC50 (96h) 0.59 mg/L (Pleuronectes platessa) (similar substance) LC50 (96h) 1.6 mg/L (Pimephales promelas) (similar substace) LC50 (96h) 3 mg/L (Brachydanio rerio) (similar substance)	ErC50 (16.9h) > 10 g/L (Pseudomonas putida) (similar substance)	EC50 (48h) 0.14 mg/L (Daphnia magna) (similar substance) EC50 (48h) 02 mg/L (Daphnia magna) (similar substance)

12.2. Persistence and degradability

Readily biodegradable

Substances	CAS Number	Persistence and Degradability
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Readily biodegradable (60% @ 28d) (similar substances)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Readily biodegradable (84% @ 28d) (similar substances)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	Log Pow: 4.3 - 5.36 (estimated) BCF: 1.1 - 1.8 (fish, estimated)
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	Log Pow: 4.3 - 5.36 (estimated) BCF: 1.1 - 1.8 (fish, estimated)

12.4. Mobility in soil

Substances	CAS Number	Mobility
Alcohols, C6-C12, ethoxylated propoxylated	68937-66-6	KOC = >4
Alcohols, C10-C16, ethoxylated propoxylated	69227-22-1	KOC = >4

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number Not restricted

UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IMDG/IMO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

IATA/ICAO

UN Number	Not restricted
UN proper shipping name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
•3Z

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 07-Feb-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H302 - Harmful if swallowed

H315 - Causes skin irritation
H318 - Causes serious eye damage

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/
NZ CCID

Disclaimer Statement

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DCA-32014

Revision Date: 31-Aug-2017 **Revision Number:** 3

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DCA-32014

Other means of Identification

Synonyms None

Hazardous Material Number: HM008547

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against Consumer use

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Aspiration Toxicity	Category 1 - H304
Skin Corrosion/Irritation	Category 2 - H315
Serious Eye Damage/Irritation	Category 1 - H318
Reproductive Toxicity	Category 1B - H360
Acute Aquatic Toxicity	Category 2 - H401
Flammable liquids.	Category 3 - H226

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H226 - Flammable liquid and vapor
H304 - May be fatal if swallowed and enters airways
H315 - Causes skin irritation
H318 - Causes serious eye damage
H360 - May damage fertility or the unborn child
H401 - Toxic to aquatic life

Precautionary Statements

Prevention
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof electrical/ventilating/lighting/equipment
P242 - Use only non-sparking tools
P243 - Take action to prevent static discharges.
P264 - Wash face, hands and any exposed skin thoroughly after handling
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P281 - Use personal protective equipment as required

Response
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P331 - Do NOT induce vomiting
P302 + P352 - IF ON SKIN: Wash with plenty of water.
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash before reuse
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P370 + P378 - In case of fire: Use water spray for extinction

Storage
P403 + P235 - Store in a well-ventilated place. Keep cool
P405 - Store locked up

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	CAS Number
Hydrotreated light petroleum distillate	64742-47-8
Ethanol	64-17-5
Fatty acids, tall-oil, ethoxylated	61791-00-2
C12-C15 Ethoxylated alcohols	68131-39-5
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4
Butyl alcohol	71-36-3

Methanol 67-56-1

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrotreated light petroleum distillate	64742-47-8	10 - 30%	Asp. Tox. 1 (H304)
Ethanol	64-17-5	10 - 30%	Eye Irrit. 2A (H319) Flam. Liq. 2 (H225)
Fatty acids, tall-oil, ethoxylated	61791-00-2	10 - 30%	Skin Irrit. 2 (H315) Eye Irrit. 2A (H319)
C12-C15 Ethoxylated alcohols	68131-39-5	10 - 30%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 3 (H412)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	10 - 30%	Skin Irrit. 2 (H315) Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 3 (H412)
Butyl alcohol	71-36-3	5 - 10%	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Corr. 1 (H318) STOT SE 3 (H335) Flam. Liq. 3 (H226)
Methanol	67-56-1	0.1 - 1%	Acute Tox. 3 (H301) Acute Tox. 3 (H311) Acute Tox. 3 (H331) Repr. 1B (H360) STOT SE 1 (H370) Flam. Liq. 2 (H225)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 30 minutes. Remove contact lenses after the first 5 minutes and continue washing. Seek immediate medical attention/advice. Suitable emergency eye wash facility should be immediately available

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention.

Ingestion Get medical attention! If vomiting occurs, keep head lower than hips to prevent aspiration. Rinse mouth. Never give anything by mouth to an unconscious person. Following ingestion, onset of symptoms may be delayed by 12 to 24 hours. Admission to hospital should be the first priority even if symptoms are absent.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes skin irritation. Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Potential reproductive hazard. May cause birth defects.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

Do NOT spray pool fires directly with water. A solid stream of water directed into hot burning liquid can cause splattering.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Use appropriate protective equipment. Remove sources of ignition. Take precautionary measures against static discharges All equipment used when handling the product must be grounded Avoid contact with skin, eyes and clothing.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Dike far ahead of liquid spill for later disposal. Soak up with inert absorbent material. Pick up and transfer to properly labeled containers. Remove ignition sources and work with non-sparking tools.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Ensure adequate ventilation. Use appropriate protective equipment. Remove sources of ignition. Ground and bond containers when transferring from one container to another. Avoid contact with eyes, skin, or clothing.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store in a cool well ventilated area. Keep from heat, sparks, and open flames.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrotreated light petroleum distillate	64742-47-8	Not applicable	Not applicable
Ethanol	64-17-5	TWA: 1000 ppm TWA: 1880 mg/m^3	STEL: 1000 ppm
Fatty acids, tall-oil, ethoxylated	61791-00-2	Not applicable	Not applicable
C12-C15 Ethoxylated alcohols	68131-39-5	Not applicable	Not applicable
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not applicable	Not applicable
Butyl alcohol	71-36-3	50 ppm	TWA: 20 ppm

Methanol	67-56-1	TWA: 200 ppm TWA: 262 mg/m^3 STEL: 250 ppm STEL: 328 mg/m^3	TWA: 200 ppm STEL: 250 ppm

Appropriate engineering controls

Engineering Controls Ensure adequate ventilation, especially in confined areas

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Organic vapor respirator.

Hand Protection Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.

Skin Protection Wear impervious protective clothing, including boots, gloves, lab coat, apron, rain jacket, pants or coverall, as appropriate, to prevent skin contact.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions Eyewash fountains and safety showers must be easily accessible.

Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Liquid
Color Colorless to Light Amber
Odor: Mild hydrocarbon
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	-44.2 °C
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	34 °C / 93.2 °F
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.918
Water Solubility	No data available
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers. Strong acids. Strong alkalis.
10.6. Hazardous decomposition products
Carbon oxides. Oxides of nitrogen.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Skin contact. Eye contact. Inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes skin irritation. Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Potential reproductive hazard. May cause birth defects.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrotreated light petroleum distillate	64742-47-8	>5000 mg/kg-bw (rat) (similar substance)	>2000 mg/kg-bw (rabbit) (similar substance)	>5.2 mg/L (rat, 4 h, vapor) (similar substance)
Ethanol	64-17-5	7060 mg/kg (Rat) 10,470 mg/kg (Rat)	> 15,800 mg/kg (Rabbit) 17,100 mg/kg (Rabbit)	124.7 mg/L (Rat) 4h
Fatty acids, tall-oil, ethoxylated	61791-00-2	> 6400 mg/kg (Rat)	No data available	No data available
C12-C15 Ethoxylated alcohols	68131-39-5	2 g/kg (Rat) 1600 mg/kg (Rat) > 5000 mg/kg (Rat)	> 2000 mg/kg (Rat) 2500 mg/kg (Rabbit)	No data available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	3500 mg/kg (Rat) > 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 0.219 mg/L (Mouse) 4h (similar substance)
Butyl alcohol	71-36-3	790 mg/kg (Rat)	3400 mg/kg (Rabbit)	> 17.6 mg/L (Rat) 4h
Methanol	67-56-1	300 mg/kg-bw (human) < 790 to 13,000 mg/kg (rat)	1000 mg/kg-bw (human) 17,100 mg/kg (rabbit)	10 mg/L (human, 4h, vapor)

Immediate, delayed and chronic health effects from exposure
Inhalation May cause central nervous system depression including headache, dizziness, drowsiness, incoordination, slowed reaction time, slurred speech, giddiness and unconsciousness.
Eye Contact Causes severe eye irritation which may damage tissue.
Skin Contact Causes skin irritation.
Ingestion Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal. Ingestion of this product may cause blindness due to the presence of methanol.

Chronic Effects/Carcinogenicity Prolonged or repeated exposure may cause reproductive system damage. May cause birth defects.

Exposure Levels
No data available

Interactive effects
No data available

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to the skin (similar substances)
Ethanol	64-17-5	Not irritating to skin in rabbits.
Fatty acids, tall-oil, ethoxylated	61791-00-2	Irritating to skin.
C12-C15 Ethoxylated alcohols	68131-39-5	May cause moderate skin irritation. (Rabbit)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Skin, rabbit: Causes moderate skin irritation. (similar substances)
Butyl alcohol	71-36-3	Causes moderate skin irritation.
Methanol	67-56-1	Non-irritating to the skin (Rabbit)

Substances	CAS Number	Serious eye damage/irritation
Hydrotreated light petroleum distillate	64742-47-8	Non-irritating to rabbit's eye (similar substances)
Ethanol	64-17-5	Causes moderate eye irritation (Rabbit)
Fatty acids, tall-oil, ethoxylated	61791-00-2	Irritating to eyes
C12-C15 Ethoxylated alcohols	68131-39-5	Risk of serious damage to eyes (Rabbit) (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Causes severe eye irritation (similar substances)
Butyl alcohol	71-36-3	Causes severe eye irritation
Methanol	67-56-1	Non-irritating to the eye (Rabbit)

Substances	CAS Number	Skin Sensitization
Hydrotreated light petroleum distillate	64742-47-8	Did not cause sensitization on laboratory animals (guinea pig) (similar substances)
Ethanol	64-17-5	Did not cause sensitization on laboratory animals
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	Did not cause sensitization on laboratory animals (guinea pig)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Did not cause sensitization on laboratory animals (similar substances)
Butyl alcohol	71-36-3	Not confirmed to cause skin or respiratory sensitization.
Methanol	67-56-1	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	Did not cause sensitization on laboratory animals
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	No information available
Methanol	67-56-1	No information available

Substances	CAS Number	Mutagenic Effects
Hydrotreated light petroleum distillate	64742-47-8	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Ethanol	64-17-5	Not regarded as mutagenic.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	In vivo tests did not show mutagenic effects. In vitro tests did not show mutagenic effects.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects. (similar substances)
Butyl alcohol	71-36-3	In vitro tests did not show mutagenic effects.
Methanol	67-56-1	The weight of evidence from available in vitro and in vivo studies indicates that this substance is not expected to be mutagenic.

Substances	CAS Number	Carcinogenic Effects

Hydrotreated light petroleum distillate	64742-47-8	Did not show carcinogenic effects in animal experiments (similar substances)
Ethanol	64-17-5	Did not show carcinogenic effects in animal experiments
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	Did not show carcinogenic effects in animal experiments
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not regarded as carcinogenic.
Butyl alcohol	71-36-3	No information available
Methanol	67-56-1	No data of sufficient quality are available.

Substances	**CAS Number**	**Reproductive toxicity**
Hydrotreated light petroleum distillate	64742-47-8	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments. (similar substances)
Ethanol	64-17-5	Animal testing did not show any effects on fertility.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Not a confirmed teratogen or embryotoxin.
Butyl alcohol	71-36-3	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.
Methanol	67-56-1	Experiments have shown reproductive toxicity effects on laboratory animals

Substances	**CAS Number**	**STOT - single exposure**
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification.
Ethanol	64-17-5	No significant toxicity observed in animal studies at concentration requiring classification.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No significant toxicity observed in animal studies at concentration requiring classification.
Butyl alcohol	71-36-3	May cause respiratory irritation.
Methanol	67-56-1	May cause disorder and damage to the Central Nervous System (CNS)

Substances	**CAS Number**	**STOT - repeated exposure**
Hydrotreated light petroleum distillate	64742-47-8	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Ethanol	64-17-5	No significant toxicity observed in animal studies at concentration requiring classification.
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No significant toxicity observed in animal studies at concentration requiring classification. (similar substances)
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No significant toxicity observed in animal studies at concentration requiring classification.
Butyl alcohol	71-36-3	No significant toxicity observed in animal studies at concentration requiring classification.
Methanol	67-56-1	No data of sufficient quality are available.

Substances	**CAS Number**	**Aspiration hazard**
Hydrotreated light petroleum distillate	64742-47-8	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Ethanol	64-17-5	Not applicable
Fatty acids, tall-oil, ethoxylated	61791-00-2	Not applicable
C12-C15 Ethoxylated alcohols	68131-39-5	No adverse health effects are expected from swallowing.
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	Aspiration into the lungs may cause chemical pneumonitis including coughing, difficulty breathing, wheezing, coughing up blood and pneumonia, which can be fatal.
Methanol	67-56-1	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

Product is not classified as hazardous to the environment.

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrotreated light petroleum distillate	64742-47-8	ErL50(72 h)>10000 mg/L (Skeletonema costatum)	LC50(96 h)>10000 mg/L (Scophthalmus maximus) NOELC(28 d)>1000 mg/L (fish)	No information available	LC50(48 h)>10000 mg/L (Acartia tonsa) NOEC(21 d)=1000 mg/L (Daphnia magna)
Ethanol	64-17-5	No information available	LC50 > 100 mg/L (Pimephales promelas)	No information available	LC50 9268 - 14,221 mg/L (Daphnia magna) LC50 5012 mg/L (Ceridaphnia dubia) NOEC 9.6 mg/L (Daphnia magna)
Fatty acids, tall-oil, ethoxylated	61791-00-2	EC50 (72h) > 44 mg/L EC50 (72h) 2.5 mg/L (Skeletonema costatum)	LC50 (95h) 7.8 mg/L (Brachydanio rerio) LC50 (96h) 45 mg/L (Cyprinodon variegatus)	EC20 (180m) >1000 mg/L	EC50 (48h) 16 mg/L (Daphnia magna) EC50 (48h) 26.8 mg/L (Acartia tonsa)
C12-C15 Ethoxylated alcohols	68131-39-5	No information available	EC50 (48h) 0.39 mg/L (Ceriodaphnia dubia) NOEC (30d) 0.28 mg/L (Pimephales promelas) NOEC (16d) 0.16 mg/L(Lepomis macrochirus)	No information available	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	EC50 (72h) 2.2 mg/L (Scendesmus subspicatus) (similar substance)	LC50 (96h) 6.7 mg/L (Danio rerio) (similar substance)	No information available	LC50 (21d) = 0.1 mg/L (Daphnia magna) LC50 (48h) = 2.15 mg/L
Butyl alcohol	71-36-3	EC50 (96h) 225 mg/L (Pseudokirchnerella subcapitata)	LC50 (96h) 1376 mg/L (Pimephales promelas)	No information available	EC50 (48h) 1328 mg/L (Daphnia magna) NOEC (21d) 4.1 mg/L (Daphnia magna) EC50 (21d) 18 mg/L (Daphnia magna)
Methanol	67-56-1	EC50 (96 h) =22000 mg/L (Pseudokirchnerella subcapitata) NOEC (8 d) =8000 mg/L (Scenedesmus quadricauda)	LC50 (96 h) =15400 mg/L (Lepomis macrochirus) EC50 (200 h) =14536 mg/L (Oryzias latipes)	IC50 (3h) > 1000 mg/L (activated sludge)	EC50 (96 h) =18260 mg/L (Dapnia magna) NOEC (21 d) =208 mg/L (Dapnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Hydrotreated light petroleum distillate	64742-47-8	Readily biodegradable (68.1% @ 28d)
Ethanol	64-17-5	No information available
Fatty acids, tall-oil, ethoxylated	61791-00-2	Readily biodegradable (74% @ 28d)
C12-C15 Ethoxylated alcohols	68131-39-5	Readily biodegradable
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	Readily biodegradable (77% @ 28d)
Butyl alcohol	71-36-3	Biodegradable. (92% @ 20d)
Methanol	67-56-1	Readily biodegradable (95% @ 20d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	-0.32
Fatty acids, tall-oil, ethoxylated	61791-00-2	MW > 700
C12-C15 Ethoxylated alcohols	68131-39-5	3
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	3.2 (estimated)

Butyl alcohol	71-36-3	1
Methanol	67-56-1	Not Bioaccumulative; BCF=1

12.4. Mobility in soil

Substances	CAS Number	Mobility
Hydrotreated light petroleum distillate	64742-47-8	No information available
Ethanol	64-17-5	No information available
Fatty acids, tall-oil, ethoxylated	61791-00-2	No information available
C12-C15 Ethoxylated alcohols	68131-39-5	No information available
Amides, tall-oil fatty, N,N-bis(hydroxyethyl)	68155-20-4	No information available
Butyl alcohol	71-36-3	KOC = 72
Methanol	67-56-1	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

IATA/ICAO

UN Number UN1993
UN proper shipping name: Flammable Liquid, N.O.S. (Contains Ethanol, Butanol)
Transport Hazard Class(es): 3
Packing Group: III
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

•3Y

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 31-Aug-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H225 - Highly flammable liquid and vapor
H226 - Flammable liquid and vapor
H301 - Toxic if swallowed
H302 - Harmful if swallowed
H304 - May be fatal if swallowed and enters airways
H311 - Toxic in contact with skin
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H331 - Toxic if inhaled
H335 - May cause respiratory irritation
H360 - May damage fertility or the unborn child
H370 - Causes damage to organs
H400 - Very toxic to aquatic life
H401 - Toxic to aquatic life
H412 - Harmful to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%

LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

DRIL-N-SLIDE™

Revision Date: 16-Sep-2015 **Revision Number:** 17

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name DRIL-N-SLIDE™

Other means of Identification

Synonyms: None

Product Code: HM003622

Recommended use of the chemical and restrictions on use

Recommended Use Lubricant

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton/Baroid Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: 61 (08) 9455 8300
Fax Number: 61 (08) 9455 5300

Product Emergency Telephone
Australia: + 61 1 800 686 951
Papua New Guinea: + 61 1 800 686 951
NewZealand: +64 800 451719

Fire, Police & Ambulance - Emergency Telephone
Australia: 000
Papua New Guinea: 000
New Zealand: 111

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard Pictograms

Signal Word	Not Hazardous
Hazard Statements	Not Classified
Precautionary Statements	
Prevention	None
Response	None
Storage	None
Disposal	None

Contains Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification

For the full text of the H-phrases mentioned in this Section, see Section 16

Classification	Not Classified
Risk Phrases	None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Eyes	In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.
Skin	Wash with soap and water.
Ingestion	Get medical attention! If vomiting occurs, keep head lower than hips to prevent aspiration. Rinse mouth. Never give anything by mouth to an unconscious person.

Symptoms caused by exposure

No significant hazards expected.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Keep container closed when not in use. Product has a shelf life of 36 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection	Not normally necessary.
Hand Protection	Impervious rubber gloves. Nitrile gloves. Neoprene gloves. Butyl rubber gloves.
Skin Protection	Normal work coveralls.
Eye Protection	Safety glasses.
Other Precautions	None known.
Environmental Exposure Controls	Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color:**	Yellowish
Odor:	Bland	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point/Range	< -30 °C
Melting Point/Range	No data available
Boiling Point/Range	240 °C / 464 °F
Flash Point	147 °C / 296 °F PMCC
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	0.86
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	1.69
Autoignition Temperature	240 °C / 464 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	0%
Liquid Density	7.18 lbs/gal
Bulk Density	53.69 lbs/ft3

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical Stability
Stable
10.3. Possibility of Hazardous Reactions
Will Not Occur
10.4. Conditions to Avoid
None anticipated
10.5. Incompatible Materials
Strong oxidizers.
10.6. Hazardous Decomposition Products
Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure
Most Important Symptoms/Effects

No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion Not determined

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable.

Substances	CAS Number	Eye damage/irritation
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable.

Substances	CAS Number	Skin Sensitization
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Respiratory Sensitization
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Mutagenic Effects
Contains no hazardous substances in concentrations above cut-off	NA	Not applicable

values according to the competent authority		

Substances	CAS Number	Carcinogenic Effects
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Reproductive toxicity
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	STOT - single exposure
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	STOT - repeated exposure
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

Substances	CAS Number	Aspiration hazard
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow

Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number: Not restricted
UN Proper Shipping Name: Not restricted
Transport Hazard Class(es): Not applicable
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals All components listed on inventory or are exempt.
EINECS Inventory This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian DSL Inventory All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

16. Other information

Date of preparation or review

Revision Date: 16-Sep-2015

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50 – Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

FE-2

Revision Date: 16-Apr-2015 **Revision Number:** 28

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name FE-2

Other means of Identification

Synonyms: None

Product Code: HM000682

Recommended use of the chemical and restrictions on use

Recommended Use Iron Control Agent

Uses Advised Against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-Mail address: fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre

24 Hour Service: - 13 11 26

Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage / Eye Irritation	Category 2 - H319

Label elements, including precautionary statements

Hazard Pictograms



Signal Word Warning

Hazard Statements H319 - Causes serious eye irritation

Precautionary Statements

Prevention P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear eye protection/face protection

Response P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention

Storage None

Disposal None

Contains

Substances	**CAS Number**
Citric acid	77-92-9

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Xi - Irritant.

Risk Phrases R36 Irritating to eyes.

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Citric acid	77-92-9	60 - 100%	Eye Irrit. 2A (H319)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes eye irritation.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special Exposure Hazards

Decomposition in fire may produce harmful gases. Organic dust in the presence of an ignition source can be explosive in high concentrations. Good housekeeping practices are required to minimize this potential.

Special protective equipment and precautions for fire fighters

Special Protective Equipment for Fire-Fighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Avoid creating and breathing dust. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Scoop up and remove.

7. Handling and storage

7.1. Precautions for Safe Handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid creating or inhaling dust. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from alkalis. Store away from oxidizers. Store in a cool, dry location. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Citric acid	77-92-9	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Dust/mist respirator. (N95, P2/P3)

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Nitrile gloves. (>= 0.35 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.

Skin Protection Normal work coveralls.

Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.

Other Precautions None known.

Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color: White
Odor: Odorless
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	2 - 2.2
Freezing Point/Range	No data available
Melting Point/Range	No data available
Boiling Point/Range	No data available
Flash Point	No data available
upper flammability limit	65
lower flammability limit	8
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.665
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	1000 °C / 1832 °F
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	192.13
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity

Not expected to be reactive.

10.2. Chemical Stability

Stable

10.3. Possibility of Hazardous Reactions

Will Not Occur

10.4. Conditions to Avoid

None anticipated

10.5. Incompatible Materials

Strong alkalis. Strong oxidizers.

10.6. Hazardous Decomposition Products

Carbon monoxide and carbon dioxide.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure Eye or skin contact, inhalation.

Sympotoms related to exposure

Most Important Symptoms/Effects

Causes eye irritation.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Citric acid	77-92-9	5400 mg/kg (Rat) 5790 mg/kg (Mouse) 11,700 mg/kg (Rat)	> 2000 mg/kg	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes eye irritation.

Skin Contact May cause mild skin irritation.

Ingestion Irritation of the mouth, throat, and stomach. May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Citric acid	77-92-9	Not irritating to skin in rabbits.

Substances	CAS Number	Eye damage/irritation
Citric acid	77-92-9	Causes severe eye irritation.

Substances	CAS Number	Skin Sensitization
Citric acid	77-92-9	Patch test on human volunteers did not demonstrate sensitization properties

Substances	CAS Number	Respiratory Sensitization
Citric acid	77-92-9	No information available

Substances	CAS Number	Mutagenic Effects
Citric acid	77-92-9	Did not show mutagenic effects in animal experiments

Substances	CAS Number	Carcinogenic Effects
Citric acid	77-92-9	Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Citric acid	77-92-9	Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Citric acid	77-92-9	No data of sufficient quality are available.

Substances	CAS Number	STOT - repeated exposure
Citric acid	77-92-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Citric acid	77-92-9	No adverse health effects are expected from swallowing.

12. Ecological Information

Ecotoxicity

Product Ecotoxicity Data

No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Citric acid	77-92-9	NOEC (8d) 425 mg/L (cell density) (Scenedesmus quadricauda) LOEC (8d) >80 mg/L (Microcystis aeruginosa)	LC50 (96h) 1516 mg/L (Lepomis macrochirus) LC50 (48h) 440 mg/L (Leuciscus idus melanotus) LC50 (96h) >100 mg/L (Pimephales promelas)	TT (72h) 485 mg/L (Entosiphon sulcatum)	TLM96 100-330 ppm (Crangon crangon) EC50 (24h) 1535 mg/L (Daphnia magna) LC50 (48h) 160 mg/L (Daphnia magna) EC50 (48h) >50 mg/L (Daphnia magna)

12.2. Persistence and degradability

Biodegradable.

Substances	CAS Number	Persistence and Degradability
Citric acid	77-92-9	Readily biodegradable (97% @ 28d)

12.3. Bioaccumulative potential

Does not bioaccumulate

Substances	CAS Number	Log Pow
Citric acid	77-92-9	-1.61 to -1.80

12.4. Mobility in soil

Substances	CAS Number	Mobility
Citric acid	77-92-9	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations. Contaminated packaging may be disposed of by: rendering packaging incapable of containing any substance, or treating packaging to remove residual contents, or treating packaging to make sure the residual

contents are no longer hazardous, or by disposing of packaging into commercial waste collection.

Environmental regulations
Not applicable

14. Transport Information

Transportation Information

UN Number:	Not restricted
UN Proper Shipping Name:	Not restricted
Transport Hazard Class(es):	Not applicable
Packing Group:	Not applicable
Environmental Hazards:	Not applicable

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components listed on inventory or are exempt.
New Zealand Inventory of Chemicals	All components listed on inventory or are exempt.
EINECS Inventory	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian DSL Inventory	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

16. Other information

Date of preparation or review

Revision Date: 16-Apr-2015

Revision Note Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
R36 - Irritating to eyes

Full text of H-Statements referred to under sections 2 and 3
H319 - Causes serious eye irritation

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight CAS – Chemical Abstracts Service EC50 – Effective Concentration 50% LC50 – Lethal Concentration 50% LD50

– Lethal Dose 50% LL50 – Lethal Loading 50% mg/kg – milligram/kilogram mg/L – milligram/liter NOEC – No Observed Effect Concentration OEL – Occupational Exposure Limit PBT – Persistent Bioaccumulative and Toxic ppm – parts per million STEL – Short Term Exposure Limit TWA – Time-Weighted Average vPvB – very Persistent and very Bioaccumulative h - hour mg/m^3 - milligram/cubic meter mm - millimeter mmHg - millimeter mercury w/w - weight/weight d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

HC-2A

Revision Date: 12-Jun-2018 **Revision Number:** 2

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name HC-2A

Other means of Identification

Synonyms None

Hazardous Material Number: HM008835

Recommended use of the chemical and restrictions on use

Recommended Use Surfactant

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Serious Eye Damage/Irritation	Category 1 - H318
Acute Aquatic Toxicity	Category 2 - H401
Chronic Aquatic Toxicity	Category 2 - H411

Label elements, including precautionary statements

Hazard Pictograms



Signal Word DANGER

Hazard Statements:
H318 - Causes serious eye damage
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

Prevention
P273 - Avoid release to the environment
P280 - Wear eye protection/face protection

Response
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/physician
P391 - Collect spillage

Storage None

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains Substances	**CAS Number**
Inner salt of alkyl amines	Proprietary

Other hazards which do not result in classification
None known

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Inner salt of alkyl amines	Proprietary	10 - 30%	Eye Corr. 1 (H318) Aquatic Acute 2 (H401) Aquatic Chronic 2 (H411)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes Immediately flush eyes with large amounts of water for at least 30 minutes. Seek prompt medical attention.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Rinse mouth with water many times. Get medical attention if symptoms occur

Symptoms caused by exposure
Causes severe eye irritation which may damage tissue.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Use water spray to cool fire exposed surfaces. Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Information

Store away from oxidizers. Store in a cool well ventilated area. Keep container closed when not in use. Product has a shelf life of 60 months.

Other Guidelines

No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring

Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Inner salt of alkyl amines	Proprietary	Not applicable	Not applicable

Appropriate engineering controls

Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)

Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.

Respiratory Protection	If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional. Dust/mist respirator. (N95, P2/P3)
Hand Protection	Use gloves which are suitable for the chemicals present in this product as well as other environmental factors in the workplace.
Skin Protection	Wear protective clothing appropriate for the work environment.
Eye Protection	Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions	Eyewash fountains and safety showers must be easily accessible.
Environmental Exposure Controls	No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear light amber
Odor:	Surfactant	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	6.5-7.5
Freezing Point / Range	0 °C
Melting Point / Range	No data available
Boiling Point / Range	100 °C / 212 °F
Flash Point	> 100 °C / > 212 °F PMCC
Evaporation rate	No data available
Vapor Pressure	< 17.5 mmHg
Vapor Density	No data available
Specific Gravity	1.12
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
Keep away from heat, sparks and flame.
10.5. Incompatible materials
Strong oxidizers.
10.6. Hazardous decomposition products
Oxides of nitrogen. Carbon monoxide and carbon dioxide. Hydrogen chloride.

11. Toxicological Information

Information on routes of exposure

Principle Route of Exposure	Eye or skin contact, inhalation.

Symptoms related to exposure

Most Important Symptoms/Effects

Causes severe eye irritation which may damage tissue.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Inner salt of alkyl amines	Proprietary	>5000 mg/kg-bw (rat)	>2000 mg/kg-bw (rat)	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.

Eye Contact Causes severe eye irritation which may damage tissue. May cause corneal injury.

Skin Contact May cause mild skin irritation.

Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels

No data available

Interactive effects

None known.

Data limitations

No data available

Substances	CAS Number	Skin corrosion/irritation
Inner salt of alkyl amines		Not irritating to skin in rabbits.

Substances	CAS Number	Serious eye damage/irritation
Inner salt of alkyl amines		Causes severe eye irritation (Rabbit)

Substances	CAS Number	Skin Sensitization
Inner salt of alkyl amines		Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Inner salt of alkyl amines		No information available

Substances	CAS Number	Mutagenic Effects
Inner salt of alkyl amines		In vitro tests did not show mutagenic effects. In vivo tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Inner salt of alkyl amines		Did not show carcinogenic effects in animal experiments

Substances	CAS Number	Reproductive toxicity
Inner salt of alkyl amines		Animal testing did not show any effects on fertility. Did not show teratogenic effects in animal experiments.

Substances	CAS Number	STOT - single exposure
Inner salt of alkyl amines		No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Inner salt of alkyl amines		No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Inner salt of alkyl amines		Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Inner salt of alkyl amines	Proprietary	EC50 (96 h) 0.55 mg/L (Desmodesmus subspicatus) EC50 (72 h) 17.2 mg/L (Scenedesmus subspicatus) EC50 (72 h) 9.86 mg/L (Scenedesmus subspicatus) EC50 (72 h) 30 mg/L (Scenedesmus subspicatus)	LC50 (96 h) 2 mg/L (Brachydanio rerio) NOEC (28 d) 16 mg/L (Oncorhynchus mykiss)	No information available	EC50 (48 h) 6.5 mg/L (Daphnia magna) NOEC (21 d) 0.9 mg/L (Daphnia magna) NOEC (21 d) 0.932 mg/L (Daphnia magna) NOEC (21 d) 2.98 mg/L (Daphnia magna) NOEC (21 d) 0.03 mg/L (Daphnia magna) NOEC (21 d) 0.065 mg/L (Daphnia magna)

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Inner salt of alkyl amines	Proprietary	Readily biodegradable (>90% @ 28d)

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow
Inner salt of alkyl amines	Proprietary	Log Pow =0.9

12.4. Mobility in soil

Substances	CAS Number	Mobility
Inner salt of alkyl amines	Proprietary	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Follow all applicable community, national or regional regulations regarding waste management methods.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN3082
UN proper shipping name: Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es): 9
Packing Group: III
Environmental Hazards: Marine Pollutant

IMDG/IMO

UN Number	UN3082
UN proper shipping name:	Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es):	9
Packing Group:	III
Environmental Hazards:	Marine Pollutant
EMS:	EmS F-A, S-F

IATA/ICAO

UN Number	UN3082
UN proper shipping name:	Environmentally Hazardous Substance, Liquid, N.O.S. (Contains Inner salt of alkyl amines)
Transport Hazard Class(es):	9
Packing Group:	III
Environmental Hazards:	Marine Pollutant

Special precautions during transport
None

HazChem Code
None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product does not comply with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply.
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply.
Basel Convention - Hazardous Waste:	Does not apply.

16. Other information

Date of preparation or review

Revision Date: 12-Jun-2018

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H318 - Causes serious eye damage
H401 - Toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

Additional information For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used

bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data

www.ChemADVISOR.com/

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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

HYDROCHLORIC ACID

Revision Date: 20-Jun-2016 **Revision Number:** 40

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name HYDROCHLORIC ACID

Other means of Identification

Synonyms None

Hazardous Material Number: HM000911

Recommended use of the chemical and restrictions on use

Recommended Use Solvent

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Acute inhalation toxicity - vapor	Category 3 - H331
Skin Corrosion/Irritation	Category 1 - H314
Serious Eye Damage/Irritation	Category 1 - H318
Specific Target Organ Toxicity - (Single Exposure)	Category 3 - H335
Substances/mixtures corrosive to metal	Category 1 - H290

Label elements, including precautionary statements

Hazard pictograms



Signal Word Danger

Hazard Statements:
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H331 - Toxic if inhaled
H335 - May cause respiratory irritation

Precautionary Statements

Prevention
P103 - Read label before use
P234 - Keep only in original container
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Response
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
P363 - Wash contaminated clothing before reuse
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P310 - Immediately call a POISON CENTER or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P390 - Absorb spillage to prevent material damage

Storage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
P406 - Store in corrosive resistant container with a resistant inner liner.

Disposal
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations

Contains

Substances	**CAS Number**
Hydrochloric acid	7647-01-0

Other hazards which do not result in classification
Chronic exposure to corrosive fumes/gases may cause erosion of the teeth followed by jaw necrosis. Bronchial irritation with chronic cough and frequent attacks of pneumonia are common. Gastrointestinal disturbances may also be seen
This mixture contains no substance considered to be persistent, bioaccumulating nor toxic (PBT).
This mixture contains no substance considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Hydrochloric acid	7647-01-0	30 - 60%	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Eye Corr. 1 (H318)

			STOT SE 3 (H335) Met. Corr. 1 (H290)

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, move victim to fresh air and seek medical attention.

Eyes In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.

Skin In case of contact, immediately flush skin with plenty of soap and water for at least 15 minutes. Get medical attention. Remove contaminated clothing and launder before reuse.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure

Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation. Harmful if inhaled.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

Water fog, carbon dioxide, foam, dry chemical.

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

May form explosive mixtures with strong alkalis. Decomposition in fire may produce harmful gases. Reaction with steel and certain other metals generates flammable hydrogen gas. Do not allow runoff to enter waterways.

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use appropriate protective equipment. Ensure adequate ventilation. Avoid contact with skin, eyes and clothing. Avoid breathing vapors. Evacuate all persons from the area.

6.2. Environmental precautions

Prevent from entering sewers, waterways, or low areas. Consult local authorities.

6.3. Methods and material for containment and cleaning up

Isolate spill and stop leak where safe. Contain spill with sand or other inert materials. Neutralize to pH of 6-8. Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling

Handling Precautions

Avoid contact with eyes, skin, or clothing. Avoid breathing vapors. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.

Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from alkalis. Store in a cool well ventilated area. Keep container closed when not in use. Store locked up. Product has a shelf life of 24 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Hydrochloric acid	7647-01-0	5 ppm	TWA: 2 ppm (Ceiling)

Appropriate engineering controls
Engineering Controls Use in a well ventilated area. Local exhaust ventilation should be used in areas without good cross ventilation.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
Acid gas respirator.

Hand Protection Chemical-resistant protective gloves (EN 374) Suitable materials for longer, direct contact (recommended: protection index 6, corresponding to > 480 minutes permeation time as per EN 374): Butyl rubber gloves. (>= 0.7 mm thickness)
This information is based on literature references and on information provided by glove manufacturers, or is derived by analogy with similar substances. Please note that in practice the working life of chemical-resistant protective gloves may be considerably shorter than the permeation time determined in accordance with EN 374 as a result of the many influencing factors (e.g. temperature). If signs of wear and tear are noticed then the gloves should be replaced. Manufacturer's directions for use should be observed because of great diversity of types.
Skin Protection Full protective chemical resistant clothing. Rubber boots
Eye Protection Chemical goggles; also wear a face shield if splashing hazard exists.
Other Precautions Eyewash fountains and safety showers must be easily accessible.
Environmental Exposure Controls Do not allow material to contaminate ground water system

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties
Physical State: Liquid
Color Clear colorless
Odor: Pungent acrid
Odor Threshold: No information available

Property	Values	Remarks/ - Method
pH:	0.8	
Freezing Point / Range	-46 °C	
Melting Point / Range	No data available	
Boiling Point / Range	110 °C / 230 °F	
Flash Point	No data available	

Evaporation rate	No data available
Vapor Pressure	26
Vapor Density	No data available
Specific Gravity	1.18
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	36.5
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong alkalis.
10.6. Hazardous decomposition products
Flammable hydrogen gas. Chlorine. Hydrogen sulfide.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Causes severe eye irritation which may damage tissue. Causes severe skin irritation with tissue destruction. May cause respiratory irritation. Harmful if inhaled.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrochloric acid	7647-01-0	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation	Harmful if inhaled. Causes severe respiratory irritation.
Eye Contact	Causes eye burns
Skin Contact	Causes severe burns. Did not cause sensitization on laboratory animals (guinea pig)
Ingestion	Causes burns of the mouth, throat and stomach.

Chronic Effects/Carcinogenicity Prolonged, excessive exposure may cause erosion of the teeth.

Exposure Levels
No data available

Interactive effects
Skin disorders.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Hydrochloric acid	7647-01-0	Causes severe burns Causes severe skin irritation with tissue destruction.

Substances	CAS Number	Serious eye damage/irritation
Hydrochloric acid	7647-01-0	Causes severe burns Causes severe eye irritation. Will damage tissue.

Substances	CAS Number	Skin Sensitization
Hydrochloric acid	7647-01-0	Did not cause sensitization on laboratory animals (guinea pig)

Substances	CAS Number	Respiratory Sensitization
Hydrochloric acid	7647-01-0	No information available

Substances	CAS Number	Mutagenic Effects
Hydrochloric acid	7647-01-0	Not regarded as mutagenic. In vitro tests did not show mutagenic effects.

Substances	CAS Number	Carcinogenic Effects
Hydrochloric acid	7647-01-0	No data of sufficient quality are available.

Substances	CAS Number	Reproductive toxicity
Hydrochloric acid	7647-01-0	Embryo and fetotoxicity has been observed in female rats exposed to maternally toxic levels of hydrogen chloride (450 mg/m^3, 1hr.). When tested at maternally toxic doses, no adverse effects on fertility, teratogenicity, or development were observed.

Substances	CAS Number	STOT - single exposure
Hydrochloric acid	7647-01-0	May cause respiratory irritation. No information available

Substances	CAS Number	STOT - repeated exposure
Hydrochloric acid	7647-01-0	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Hydrochloric acid	7647-01-0	Not applicable

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Hydrochloric acid	7647-01-0	No information available	LC50 282 mg/L (Gambusia affinis) LC50 20.5 mg/L (Lepomis macrochirus) LC50 (96h) 3.25 – 3.5 (pH) (Lepomis macrochirus)	EC50 (3h) >= 5 and <= 5.5 (pH) (Activated sludge, domestic)	EC50 (48 h) 4.92 mg/L (Daphnia magna)

12.2. Persistence and degradability
The methods for determining biodegradability are not applicable to inorganic substances.

Substances	CAS Number	Persistence and Degradability
Hydrochloric acid	7647-01-0	The methods for determining biodegradability are not applicable to inorganic substances.

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow

Hydrochloric acid	7647-01-0	LogKow -2.65

12.4. Mobility in soil

Substances	CAS Number	Mobility
Hydrochloric acid	7647-01-0	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations. Substance should NOT be deposited into a sewage facility.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number UN1789
UN proper shipping name: Hydrochloric Acid Solution
Transport Hazard Class(es): 8
Packing Group: II
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

2R

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances) This product, and all its components, complies with EINECS
US TSCA Inventory All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL) All components listed on inventory or are exempt.

Poisons Schedule number

S6

International Agreements

Montreal Protocol - Ozone Depleting Substances: Does not apply
Stolkhom Convention - Persistent Organic Pollutants: Does not apply
Rotterdam Convention - Prior Informed Consent: Does not apply

Basel Convention - Hazardous Waste: Does not apply

16. Other information

Date of preparation or review

Revision Date: 20-Jun-2016

Revision Note
SDS sections updated: 2

Full text of H-Statements referred to under sections 2 and 3
H290 - May be corrosive to metals
H314 - Causes severe skin burns and eye damage
H318 - Causes serious eye damage
H335 - May cause respiratory irritation
H331 - Toxic if inhaled
H332 - Harmful if inhaled

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
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End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

NITROGEN LIQUEFIED

Revision Date: 29-Aug-2017 **Revision Number:** 30

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name NITROGEN LIQUEFIED

Other means of Identification

Synonyms None

Hazardous Material Number: HM001654

Recommended use of the chemical and restrictions on use

Recommended Use Fluid

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier Halliburton Australia Pty. Ltd.
15 Marriott Road, Jandakot, WA 6164
Australia
ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951
Global Incident Response Access Code: 334305
Contract Number: 14012

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Gases under pressure.	Refrigerated liquefied gas - H281

Label elements, including precautionary statements

Hazard Pictograms

Signal Word WARNING

Hazard Statements: H281 - Contains refrigerated gas; may cause cryogenic burns or injury

Precautionary Statements

Prevention	P282 - Wear cold insulating gloves and either face shield or eye protection.
Response	P336 - Thaw frosted parts with lukewarm water. Do no rub affected area P315 - Get immediate medical advice/attention
Storage	P403 - Store in a well-ventilated place
Disposal	None

Contains

Substances	**CAS Number**
Nitrogen	7727-37-9

Other hazards which do not result in classification

This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

For the full text of the H-phrases mentioned in this Section, see Section 16

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Nitrogen	7727-37-9	60 - 100%	Refrigerated Liquefied Gas Compressed gas (H280)

4. First aid measures

Description of necessary first aid measures

Inhalation	If inhaled, move victim to fresh air and seek medical attention.
Eyes	In case of contact, or suspected contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention immediately after flushing.
Skin	For exposure to liquid, immediately warm frostbite area with warm water (not to exceed 105 F or 41 C). In case of massive exposure, remove clothing while showering with warm water. Get medical attention.
Ingestion	Get immediate medical attention.

Symptoms caused by exposure

Reduces oxygen available for breathing. May cause freeze burns.

Medical Attention and Special Treatment

Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment

Suitable Extinguishing Media

All standard fire fighting media

Extinguishing media which must not be used for safety reasons

None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire

Containers may explode (due to the build-up of pressure) when exposed to extreme heat

Special protective equipment and precautions for fire fighters

Special protective equipment for firefighters

Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Ensure adequate ventilation.

6.2. Environmental precautions
None known.

6.3. Methods and material for containment and cleaning up
Isolate spill and stop leak where safe.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid contact with eyes, skin, or clothing. Ensure adequate ventilation. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store in a cool, dry location. Keep container closed when not in use.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Nitrogen	7727-37-9	1000 ppm	:

Appropriate engineering controls
Engineering Controls Use in a well ventilated area.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection If engineering controls and work practices cannot keep exposure below occupational exposure limits or if exposure is unknown, wear a NIOSH certified, European Standard EN 149, AS/NZS 1715:2009, or equivalent respirator when using this product. Selection of and instruction on using all personal protective equipment, including respirators, should be performed by an Industrial Hygienist or other qualified professional.
In high concentrations, supplied air respirator or a self-contained breathing apparatus.
Hand Protection Substantial leather work gloves.
Skin Protection Normal work coveralls.
Eye Protection None known.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State:	Liquid	**Color**	Clear colorless
Odor:	Odorless	**Odor Threshold:**	No information available

Property Remarks/ - Method	Values
pH:	No data available
Freezing Point / Range	-210 °C
Melting Point / Range	No data available
Boiling Point / Range	-195 °C / -319 °F
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	608
Vapor Density	0.97
Specific Gravity	0.8
Water Solubility	Insoluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

Molecular Weight	28
VOC Content (%)	No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
None known.
10.6. Hazardous decomposition products
None known.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
Reduces oxygen available for breathing. May cause freeze burns.

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Nitrogen	7727-37-9	No data available	No data available	No data available

Immediate, delayed and chronic health effects from exposure

Inhalation	Reduces oxygen available for breathing.
Eye Contact	Contact with liquid causes frostbite.
Skin Contact	Contact of material on skin may result in frostbite.
Ingestion	Irritation of the mouth, throat, and stomach.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

Substances	CAS Number	Skin corrosion/irritation
Nitrogen	7727-37-9	Contact with liquid causes frostbite.

Substances	CAS Number	Serious eye damage/irritation
Nitrogen	7727-37-9	Non-irritating to the eye

Substances	CAS Number	Skin Sensitization
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Respiratory Sensitization
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Mutagenic Effects
Nitrogen	7727-37-9	Not regarded as mutagenic.

Substances	CAS Number	Carcinogenic Effects
Nitrogen	7727-37-9	No information available

Substances	CAS Number	Reproductive toxicity
Nitrogen	7727-37-9	No information available

Substances	CAS Number	STOT - single exposure
Nitrogen	7727-37-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	STOT - repeated exposure
Nitrogen	7727-37-9	No significant toxicity observed in animal studies at concentration requiring classification.

Substances	CAS Number	Aspiration hazard
Nitrogen	7727-37-9	Not applicable

12. Ecological Information

Ecotoxicity

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Nitrogen	7727-37-9	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Nitrogen	7727-37-9	No information available

12.3. Bioaccumulative potential

Substances	CAS Number	Log Pow

Nitrogen	7727-37-9	No information available

12.4. Mobility in soil

Substances	CAS Number	Mobility
Nitrogen	7727-37-9	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Disposal should be made in accordance with federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

Australia ADG

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable

IMDG/IMO

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable
EMS: EmS F-C, S-V

IATA/ICAO

UN Number UN1977
UN proper shipping name: Nitrogen, Refrigerated Liquid
Transport Hazard Class(es): 2.2
Packing Group: Not applicable
Environmental Hazards: Not applicable

Special precautions during transport

None

HazChem Code

2T

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.

New Zealand Inventory of Chemicals	All components are listed on the NZIoC or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number
None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stockholm Convention - Persistent Organic Pollutants:	Does not apply
Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 29-Aug-2017

Revision Note
SDS sections updated:
2

Full text of H-Statements referred to under sections 2 and 3
H281 - Contains refrigerated gas; may cause cryogenic burns or injury

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

Disclaimer Statement

This information is furnished without warranty, expressed or implied, as to accuracy or completeness. The information is obtained from various sources including the manufacturer and other third party sources. The information may not be valid under all conditions nor if this material is used in combination with other materials or in any process. Final determination of suitability of any material is the sole responsibility of the user.

End of Safety Data Sheet

HALLIBURTON

SAFETY DATA SHEET

SOURSCAV®

Revision Date: 04-Mar-2016 **Revision Number:** 24

1. Product Identifier & Identity for the Chemical

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

1.1. Product Identifier

Product Name SOURSCAV®

Other means of Identification

Synonyms None

Product Code: HM003675

Recommended use of the chemical and restrictions on use

Recommended Use Hydrogen Sulfide Scavenger

Uses advised against No information available

Supplier's name, address and phone number

Manufacturer/Supplier

Halliburton Australia Pty. Ltd.
15 Marriott Road
Jandakot
WA 6164
Australia

ACN Number: 009 000 775
Telephone Number: + 61 1 800 686 951
Fax Number: 61 (08) 9455 5300

E-mail Address fdunexchem@halliburton.com

Emergency phone number

+ 61 1 800 686 951

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 000 (exchange): - 1100

2. Hazard Identification

Statement of Hazardous Nature Non-Hazardous according to the criteria of the 3rd Revised Edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Non-Dangerous Goods according to the criteria of ADG.

Classification of the hazardous chemical

Not classified

Label elements, including precautionary statements

Hazard pictograms

Signal Word Not Hazardous

Hazard Statements Not Classified

Precautionary Statements

Prevention None
Response None
Storage None
Disposal None

Contains

Substances	**CAS Number**
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA

Other hazards which do not result in classification
This substance is not considered to be persistent, bioaccumulating nor toxic (PBT).
This substance is not considered to be very persistent nor very bioaccumulating (vPvB).

Australia Classification
For the full text of the H-phrases mentioned in this Section, see Section 16

Classification Not Classified
Risk Phrases None

3. Composition/information on Ingredients

Substances	CAS Number	PERCENT (w/w)	GHS Classification - Australia
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	60 - 100%	Not Applicable

4. First aid measures

Description of necessary first aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Eyes In case of contact, immediately flush eyes with plenty of water for at least 15 minutes and get medical attention if irritation persists.

Skin Wash with soap and water. Get medical attention if irritation persists.

Ingestion Do NOT induce vomiting. Give nothing by mouth. Obtain immediate medical attention.

Symptoms caused by exposure
No significant hazards expected.

Medical Attention and Special Treatment
Notes to Physician Treat symptomatically

5. Fire Fighting Measures

Suitable extinguishing equipment
Suitable Extinguishing Media
Water fog, carbon dioxide, foam, dry chemical.
Extinguishing media which must not be used for safety reasons
None known.

Specific hazards arising from the chemical

Special exposure hazards in a fire
Decomposition in fire may produce harmful gases.

Special protective equipment and precautions for fire fighters
Special protective equipment for firefighters
Full protective clothing and approved self-contained breathing apparatus required for fire fighting personnel.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures
Use appropriate protective equipment. Avoid contact with skin, eyes and clothing. Avoid creating and breathing dust. Ensure adequate ventilation.

6.2. Environmental precautions
None known.

6.3. Methods and material for containment and cleaning up
Scoop up and remove.

7. Handling and storage

7.1. Precautions for safe handling
Handling Precautions
Avoid creating or inhaling dust. Avoid contact with eyes, skin, or clothing. Ensure adequate ventilation. Wash hands after use. Launder contaminated clothing before reuse. Use appropriate protective equipment.
Hygiene Measures
Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities
Storage Information
Store away from acids. Store away from oxidizers. Store in a cool, dry location. Keep container closed when not in use. Store away from direct sunlight. Product has a shelf life of 36 months.
Other Guidelines
No information available

8. Exposure Controls/Personal Protection

Control parameters - exposure standards, biological monitoring
Exposure Limits

Substances	CAS Number	Australia NOHSC	ACGIH TLV-TWA
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	Not applicable	Not applicable

Appropriate engineering controls
Engineering Controls A well ventilated area to control dust levels.

Personal protective equipment (PPE)
Personal Protective Equipment If engineering controls and work practices cannot prevent excessive exposures, the selection and proper use of personal protective equipment should be determined by an industrial hygienist or other qualified professional based on the specific application of this product.
Respiratory Protection Not normally needed. But if significant exposures are possible then the following respirator is recommended:
Dust/mist respirator. (N95, P2/P3)
Hand Protection Normal work gloves.
Skin Protection Normal work coveralls.
Eye Protection Wear safety glasses or goggles to protect against exposure.
Other Precautions None known.
Environmental Exposure Controls No information available

9. Physical and Chemical Properties

9.1. Information on basic physical and chemical properties

Physical State: Solid
Color Light yellow-green
Odor: Mild burnt sugar
Odor Threshold: No information available

Property Remarks/ - Method	Values
pH:	4-5.5
Freezing Point / Range	No data available
Melting Point / Range	No data available
Boiling Point / Range	No data available
Flash Point	No data available
Evaporation rate	No data available
Vapor Pressure	No data available
Vapor Density	No data available
Specific Gravity	1.73
Water Solubility	Soluble in water
Solubility in other solvents	No data available
Partition coefficient: n-octanol/water	No data available
Autoignition Temperature	No data available
Decomposition Temperature	No data available
Viscosity	No data available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

VOC Content (%) No data available

10. Stability and Reactivity

10.1. Reactivity
Not expected to be reactive.
10.2. Chemical stability
Stable
10.3. Possibility of hazardous reactions
Will Not Occur
10.4. Conditions to avoid
None anticipated
10.5. Incompatible materials
Strong oxidizers. Strong acids.
10.6. Hazardous decomposition products
Carbon monoxide and carbon dioxide. Metal oxides.

11. Toxicological Information

Information on routes of exposure
Principle Route of Exposure Eye or skin contact, inhalation.

Symptoms related to exposure
Most Important Symptoms/Effects
No significant hazards expected.

Numerical measures of toxicity

Toxicology data for the components

Substances	CAS Number	LD50 Oral	LD50 Dermal	LC50 Inhalation
Contains no hazardous	NA	No data available	No data available	No data available

substances in concentrations above cut-off values according to the competent authority				

Immediate, delayed and chronic health effects from exposure

Inhalation May cause mild respiratory irritation.
Eye Contact May cause mild eye irritation.
Skin Contact May cause mild skin irritation.
Ingestion May cause abdominal pain, vomiting, nausea, and diarrhea. May be harmful if swallowed.

Chronic Effects/Carcinogenicity No data available to indicate product or components present at greater than 0.1% are chronic health hazards.

Exposure Levels
No data available

Interactive effects
None known.

Data limitations
No data available

12. Ecological Information

Ecotoxicity
Product Ecotoxicity Data
No data available

Substance Ecotoxicity Data

Substances	CAS Number	Toxicity to Algae	Toxicity to Fish	Toxicity to Microorganisms	Toxicity to Invertebrates
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available	No information available	No information available	No information available

12.2. Persistence and degradability

Substances	CAS Number	Persistence and Degradability
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.3. Bioaccumulative potential
Does not bioaccumulate.

Substances	CAS Number	Log Pow
Contains no hazardous substances in	NA	No information available

concentrations above cut-off values according to the competent authority		

12.4. Mobility in soil

Substances	CAS Number	Mobility
Contains no hazardous substances in concentrations above cut-off values according to the competent authority	NA	No information available

12.6. Other adverse effects

Endocrine Disruptor Information

This product does not contain any known or suspected endocrine disruptors

13. Disposal Considerations

Safe handling and disposal methods

Bury in a licensed landfill according to federal, state, and local regulations.

Disposal of any contaminated packaging

Follow all applicable national or local regulations.

Environmental regulations

Not applicable

14. Transport Information

Transportation Information

UN Number	Not restricted
UN proper shipping name	Not restricted
Transport Hazard Class(es)	Not applicable
Packing Group:	Not applicable
Environmental Hazards	Not applicable

Special precautions during transport

None

HazChem Code

None Allocated

15. Regulatory Information

Safety, health and environmental regulations specific for the product

International Inventories

Australian AICS Inventory	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
New Zealand Inventory of Chemicals	All components are listed on the AICS or are subject to a relevant exemption, permit, or assessment certificate.
EINECS (European Inventory of Existing Chemical Substances)	This product, and all its components, complies with EINECS
US TSCA Inventory	All components listed on inventory or are exempt.
Canadian Domestic Substances List (DSL)	All components listed on inventory or are exempt.

Poisons Schedule number

None Allocated

International Agreements

Montreal Protocol - Ozone Depleting Substances:	Does not apply
Stolkhom Convention - Persistent Organic Pollutants:	Does not apply

Rotterdam Convention - Prior Informed Consent:	Does not apply
Basel Convention - Hazardous Waste:	Does not apply

16. Other information

Date of preparation or review

Revision Date: 04-Mar-2016

Revision Note
SDS sections updated: 2

Full text of R-phrases referred to under Sections 2 and 3
None

Full text of H-Statements referred to under sections 2 and 3
None

Additional information

For additional information on the use of this product, contact your local Halliburton representative.

For questions about the Safety Data Sheet for this or other Halliburton products, contact Chemical Stewardship at 1-580-251-4335.

Key abreviations or acronyms used
bw – body weight
CAS – Chemical Abstracts Service
EC50 – Effective Concentration 50%
LC50 – Lethal Concentration 50%
LD50 – Lethal Dose 50%
LL50 – Lethal Loading 50%
mg/kg – milligram/kilogram
mg/L – milligram/liter
NOEC – No Observed Effect Concentration
OEL – Occupational Exposure Limit
PBT – Persistent Bioaccumulative and Toxic
ppm – parts per million
STEL – Short Term Exposure Limit
TWA – Time-Weighted Average
vPvB – very Persistent and very Bioaccumulative
h - hour
mg/m^3 - milligram/cubic meter
mm - millimeter
mmHg - millimeter mercury
w/w - weight/weight
d - day

Key literature references and sources for data
www.ChemADVISOR.com/
NZ CCID

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End of Safety Data Sheet

FlowProfiler Gas Tracer SDS

SAFETY DATA SHEET

Date-Issued: 05-2015
SDS Ref. No: CFT_Aus
Date-Revised: 04-Apr-2019
Revision No:003

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifiers

Product name	:	Chemical Frac Tracer
Product number	:	APW 001, APW 002, APW 003, APW 004, APW 005, APW 006, APW 007, APW 008, APW 009, APW 010, APW 011, APW 012, APW 013, APW 014, APW 015, APW 016, APW 017, APW 018, APW 019, APW 020, APW 021, APW 022, APW 023, APW 024, APW 025, APW 026, APW 027, APW 028, APW 029, APW 030, APW 031, APW 032, APW 033, APW 034, APW 035, APW 036, APW 037, APW 038, APW 039, APW 040, APW 041, APW 042, APW 043, APW 044, APW 045, APW 046, APW 047, APW 048, APW 049, APW 050, APW 051
Generic name	:	APW 001, APW 002, APW 003, APW 004, APW 005, APW 006, APW 007, APW 008, APW 009, APW 010, APW 011, APW 012, APW 013, APW 014, APW 015, APW 016, APW 017, APW 018, APW 019, APW 020, APW 021, APW 022, APW 023, APW 024, APW 025, APW 026, APW 027, APW 028, APW 029, APW 030, APW 031, APW 032, APW 033, APW 034, APW 035, APW 036, APW 037, APW 038, APW 039, APW 040, APW 041, APW 042, APW 043, APW 044, APW 045, APW 046, APW 047, APW 048, APW 049, APW 050, APW 051

1.2 Relevant identified used of the substance or mixture and uses advised against

Identified uses	:	Diagnostic
Uses advised against	:	Not available

1.3 Details of the supplier of the product and safety data sheet

Company	:	ProTechnics Division of Core Laboratories 6510 W. Sam Houston Parkway N. Houston, Texas 77041
Telephone	:	+1 713 328 2320
Email	:	david.trinker@corelab.com

Australia contact information

Company	:	ProTechnics Intenational Division of Core Laboratories 31-35 George St. Thebarton, SA, Australia 5031
Telephone	:	(08) 8152 0244

1.4 Emergency telephone number(s)

Australia Emergency Contact Information

Poisons Information Centre : 13 11 26 (24 hour)
Ambulance, Fire, Police: 000

U.S. Emergency Contact Information

Emergency phone number	:	+1 713 328 2320
Transportation emergency	:	+1 800 535 5053 (inside US)
	:	+1 352 323 3500 collect (outside US)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS classification in accordance with 29 CFR 1910 (OSHA HCS)
Skin irritation (Category 2), H315
Eye irritation (Category 2), H319
Specific target organ toxicity – single exposure (Category 3), Respiratory system, H335

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word Warning

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statement(s)

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove affected person into fresh air and keep at rest in a position comfortable for breathing.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Substance/ mixture Mixture

Ingredient	CAS/Exempt No	Percent	Hazardous
Proprietary Ingredient supplied as 10% w/v Aqueous Solution	Proprietary	10	No
Water	7732-18-5	90	No

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
Move person into fresh air. If cough or other symptoms develop, consult a physician.

In case of skin contact
Remove contaminated clothing including shoes and immediately wash affected area with plenty of soap and water. If irritation continues, consult a physician. Wash contaminated clothing and shoes before reuse.

In case of eye contact
Immediately flush eyes with plenty of water for two to three minutes. Remove any contact lenses and continue flushing for 15 minutes. If irritation continues, consult a physician.

If swallowed
Wash out mouth with water and keep at rest. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, halogenated hydrogen gas.

5.3 Advice for firefighters

As in any fire, wear full protective clothing and equipment.

5.4 Further information

No data available.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours or mist. Evacuate personnel to safe areas.

6.2 Environmental precautions

Do not let product enter drains, if safe to do so.

6.3 Methods and materials for containment and cleanup

Construct temporary dikes of dirt or any appropriate readily available material to prevent spreading of the material. Cover with appropriate absorbent and sweep or shovel into an appropriate container.

6.4 Reference to other sections

For protective clothing, see Section 8. For disposal, see Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of aerosols. Provide adequate exhaust ventilation at places where aerosols are formed. For precautions, see Section 2.2. Handle and use in a manner consistent with good industrial/manufacturing techniques and practices.

7.2 Conditions for safe storage

Keep container tightly closed in a dry, cool, and well-ventilated place. Do not store with, or close to, strong acids.

7.3 Specific end uses(s)

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
No PELs, TLVs, or OELs for this product or its ingredients are listed in the current issue of ACGIH's Guide to Occupational Exposure Values, nor have they been determined by the manufacturer.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

Personal protective equipment

Eye/face protection
Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin protection
Handle with chemical-resistant gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection
Impervious clothing. The type of protective equipment must be selected according to the amount of dangerous substance at the specific workplace.

Control of environmental exposure
Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: aqueous liquid Color: translucent
b)	Odor	Odorless
c)	Boiling point	Approximately 100°C

d)	Freeze point	0°C
e)	Density	1.05 g/mL
f)	Flash point	Not flammable
g)	pH	Approximately 9
h)	Evaporation factor	Not determined
i)	Solubility	Soluble in water
j)	Vapor pressure	Not determined
k)	Oxidizing properties	Not determined
l)	Vapor density	Not determined
m)	Viscosity	Not determined

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

Strong acids. Oxidizing materials.

10.2 Chemical stability

The product is stable under normal ambient conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Will not polymerize.

10.4 Conditions to avoid

Extreme cold.

10.5 Incompatible materials

Strong acids. Oxidizing materials.

10.6 Hazardous decomposition products

None.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity – oral
Based on available data the classification criteria are not met.

Acute toxicity – dermal
Based on available data the classification criteria are not met.

Acute toxicity – inhalation
Based on available data the classification criteria are not met.

Skin corrosion/irritation
Skin irritant 2 – H315 Causes skin irritation.

Serious eye damage/irritation
Eye irritant 2 – H319 May cause severe eye irritation.

Respiratory sensitization
Based on available data the classification criteria are not met.

Skin sensitization
Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity – in vitro
Based on available data the classification criteria are not met.

Genotoxicity- in vivo
Based on available data the classification criteria are not met.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Reproductive toxicity – fertility
Based on available data the classification criteria are not met.

Reproductive toxicity – development
Based on available data the classification criteria are not met.

Specific target organ toxicity – single exposure
STOT SE 3 – H335 May cause respiratory irritation.

Specific target organ toxicity – repeated exposure
Based on available data the classification criteria are not met.

Aspiration hazard
Not anticipated to present an aspiration hazard, based on chemical structure.

Additional information
RTECS: Not available.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

Presumed to be persistent.

12.3 Bio-accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment are not available as chemical safety assessment not required/ not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Dispose of at a supervised appropriate waste disposal facility according to current applicable laws and regulations and product characteristics at time of disposal.

Contaminated packaging
Contaminated containers should be cleaned and disposed of in the same manner as the product in accordance with applicable regulations.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods.

IMDG
Not dangerous goods.

IATA
Not dangerous goods.

15. REGULATORY INFORMATION

HSNO Regulatory Information: Not available within New Zealand.

Regulatory information is based on U.S. regulations. Globally Harmonized System (GHS) of classification and labelling of chemicals in accordance with U.S. 29 CFR 1910 (OSHA HCS).

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
SAR 311/312: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 311/312.

CERCLA (Comprehensive Response, Compensation, and Liability Act)
Not Applicable.

TSCA (Toxic Substance Control Act)
The components of this product are in compliance with the chemical notification requirements of TSCA.

German Water Endangerment Class
WGK: 1

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16. OTHER INFORMATION

HMIS Rating

Health Hazard:	1
Chronic Health Hazard:	
Flammability:	0
Physical Hazard:	0

NFPA Rating

Health Hazard:	1
Fire Hazard:	0
Reactivity Hazard:	0

MANUFACTURER DISCLAIMER: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses which infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Prepared by: ProTechnics Environmental Compliance Department

ProTechnics Division of Core Laboratories
6510 W. Sam Houston Parkway N.
Houston, Texas 77041

Date of revision: 04-Apr-2019

Contact information: +1 713 328 2320

SAFETY DATA SHEET

Date-Issued: 01-2015
SDS Ref. No: APG_Aus
Date-Revised: 04-Apr-2019
Revision No:002

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifiers

Product name	:	Gas Frac Tracer
Product number	:	APG 001, APG 002, APG 003, APG 004, APG 005, APG 006, APG 007, APG 008, APG 009, APG 010, APG 011, APG 012, APG 013, APG 014, APG 015, APG 016
Generic name	:	APG 001, APG 002, APG 003, APG 004, APG 005, APG 006, APG 007, APG 008, APG 009, APG 010, APG 011, APG 012, APG 013, APG 014, APG 015, APG 016

1.2 Relevant identified used of the substance or mixture and uses advised against

Identified uses	:	Diagnostic
Uses advised against	:	Not available

1.3 Details of the supplier of the product and safety data sheet

Company	:	ProTechnics Division of Core Laboratories 6510 W. Sam Houston Parkway N. Houston, Texas 77041
Telephone	:	+1 713 328 2320
Email	:	david.trinker@corelab.com

Australia contact information

Company	:	ProTechnics Intenational Division of Core Laboratories 31-35 George St. Thebarton, SA, Australia 5031
Telephone	:	(08) 8152 0244

1.4 Emergency telephone number(s)

Australia Emergency Contact Information

Poisons Information Centre	:	13 11 26 (24 hour)
Ambulance, Fire, Police:		000

U.S. Emergency Contact Information

Emergency phone number	:	+1 713 328 2320
Transportation emergency	:	+1 800 535 5053 (inside US)
	:	+1 352 323 3500 collect (outside US)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS classification in accordance with 29 CFR 1910 (OSHA HCS)
Skin irritation (Category 2), H315
Eye irritation (Category 2A), H319
Specific target organ toxicity – single exposure (Category 3), Respiratory system, H335

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word — Warning

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

Precautionary statement(s)

P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.
P280	Wear protective gloves.
P280	Wear eye protection/ face protection.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove affected person into fresh air and keep at rest in a position comfortable for breathing.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.
P337 + P313	If eye irritation persists: Get medical advice/ attention.
P362	Take off contaminated clothing and wash before reuse.
P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P403 + P235	Store in a well-ventilated place. Keep cool.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Substance/ mixture — Substance

Ingredient	CAS/Exempt No	Percent	Hazardous
Proprietary Ingredient	Proprietary	100	No

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
Move person into fresh air. If cough or other symptoms develop, consult a physician.

In case of skin contact
Remove contaminated clothing including shoes and immediately wash affected area with plenty of soap and water. If irritation continues, consult a physician. Wash contaminated clothing and shoes before reuse.

In case of eye contact
Immediately flush eyes with plenty of water for two to three minutes. Remove any contact lenses and continue flushing for 15 minutes. If irritation continues, consult a physician.

If swallowed
Do NOT induce vomiting. Wash out mouth with water and keep at rest. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Carbon dioxide, dry chemical powder, alcohol or polymer foam.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, halogenated hydrogen gas.

5.3 Advice for firefighters

As in any fire, wear full protective clothing and equipment.

5.4 Further information

Use water spray to cool unopened containers.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapors, mist, or gas. Ensure adequate ventilation. Evacuate personnel to safe areas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleanup

Construct temporary dikes of dirt or any appropriate readily available material to prevent spreading of the material. Collect spillage with an electrically powered vacuum cleaner or by wet-brushing and place in container for disposal according to local regulations. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For protective clothing, see Section 8. For disposal, see Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapors or mist. Provide adequate exhaust ventilation at places where aerosols are formed. For precautions, see Section 2.2. Handle and use in a manner consistent with good industrial/manufacturing techniques and practices.

7.2 Conditions for safe storage

Keep container tightly closed in a dry, cool, and well-ventilated place.

7.3 Specific end uses(s)

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
No PELs, TLVs, or OELs for this product or its ingredients are listed in the current issue of ACGIH's Guide to Occupational Exposure Values nor have they been determined by the manufacturer.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday. Use general dilution ventilation and/or local exhaust ventilation to control airborne exposures to below relevant Exposure Limits and/or control dust/fume/gas/mist/vapor/spray.

Personal protective equipment

Eye/face protection
Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin protection
Handle with chemical-resistant gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove’s outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection
Impervious clothing. The type of protective equipment must be selected according to the amount of dangerous substance at the specific workplace.

Control of environmental exposure
Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: liquid Color: colorless
b)	Odor	Odorless.
c)	Boiling point	Not determined.
d)	Freeze point	Not determined.
e)	Density	Not determined.
f)	Flash point	Not determined.
g)	pH	Not determined.
h)	Evaporation factor	Not determined.
i)	Solubility	Not soluble in water.
j)	Vapor pressure	Not determined.
k)	Oxidizing properties	Not determined.
l)	Vapor density	Not determined.
m)	Viscosity	Not determined.
n)	Auto-ignition temperature	Not determined.
o)	Explosive properties	Not determined.
p)	Percent volatile	100 %

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Will not polymerize.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Other decomposition products – No data available.
In the event of a fire: see Section 5.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity – oral
Based on available data the classification criteria are not met.

Acute toxicity – dermal
Based on available data the classification criteria are not met.

Acute toxicity – inhalation
Based on available data the classification criteria are not met.

Skin corrosion/irritation
Skin irritant 2 – H315 Causes skin irritation.

Serious eye damage/irritation
Eye irritant 2 – H319 May cause severe eye irritation.

Respiratory sensitization
Based on available data the classification criteria are not met.

Skin sensitization
Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity – in vitro
Based on available data the classification criteria are not met.

Genotoxicity- in vivo
Based on available data the classification criteria are not met.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Reproductive toxicity – fertility
Based on available data the classification criteria are not met.

Reproductive toxicity – development
Based on available data the classification criteria are not met.

Specific target organ toxicity – single exposure
STOT SE 3 – H335 May cause respiratory irritation.

Specific target organ toxicity – repeated exposure
Based on available data the classification criteria are not met.

Aspiration hazard
Not anticipated to present an aspiration hazard, based on chemical structure.

Additional information
RTECS: Not available.

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

Presumed to be persistent.

12.3 Bio-accumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment are not available as chemical safety assessment not required/ not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Dispose of at a supervised appropriate waste disposal facility according to current applicable laws and regulations and product characteristics at time of disposal.

Contaminated packaging
Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)
Not dangerous goods.

IMDG
Not dangerous goods.

IATA
Not dangerous goods.

15. REGULATORY INFORMATION

HSNO Regulatory Information: Not available within New Zealand.

Regulatory information is based on U.S. regulations. Globally Harmonized System (GHS) of classification and labelling of chemicals in accordance with U.S. 29 CFR 1910 (OSHA HCS).

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
SAR 311/312: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 311/312.

CERCLA (Comprehensive Response, Compensation, and Liability Act)
Not Applicable.

TSCA (Toxic Substance Control Act)
The components of this product are in compliance with the chemical notification requirements of TSCA.

German Water Endangerment Class
WGK: 1

16. OTHER INFORMATION

HMIS Rating

Health Hazard:	1
Chronic Health Hazard:	
Flammability:	0
Physical Hazard:	0

NFPA Rating

Health Hazard:	1
Fire Hazard:	0
Reactivity Hazard:	0

MANUFACTURER DISCLAIMER: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses which infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Prepared by: ProTechnics Environmental Compliance Department

ProTechnics Division of Core Laboratories
6510 W. Sam Houston Parkway N.
Houston, Texas 77041

Contact information: +1 713 328 2320

Date of revision: 04-Apr-2019

SAFETY DATA SHEET

Date-Issued: 04-2019
SDS Ref. No: APFAW_Aus
Date-Revised:
Revision No:000

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifiers

Product name	:	Water Flow Assurance Tracer
Product number	:	APFAW 001 or APFAW 002
Generic name	:	APFAW 001 or APFAW 002

1.2 Relevant identified used of the substance or mixture and uses advised against

Identified uses	:	Diagnostic
Uses advised against	:	Not available

1.3 Details of the supplier of the safety data sheet

Company	:	ProTechnics Division of Core Laboratories 6510 W. Sam Houston Parkway N. Houston, Texas 77041
Telephone	:	+1 713 328 2320
Email	:	david.trinker@corelab.com

Australia contact information

Company	:	ProTechnics International Division of Core Laboratories 31-35 George St. Thebarton, SA, Australia 5031
Telephone	:	(08) 8152 0244

1.4 Emergency telephone number(s)

Australia Emergency Contact Information

Poisons Information Centre	:	13 11 26 (24 hour)
Ambulance, Fire, Police	:	000

U.S. Emergency Contact Information

Emergency phone number	:	+1 713 328 2320
Transportation emergency	:	+1 800 535 5053 (inside US)
	:	+1 352 323 3500 collect (outside US)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS classification in accordance with 29 CFR 1910 (OSHA HCS)
Acute toxicity, Oral (Category 4), H302
Respiratory Sensitization (Category 1)
Skin Sensitization (Category 1)

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word	Warning
Hazard statement(s)	
H302	Harmful if swallowed
Precautionary statement(s)	
P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264	Wash skin thoroughly after handling.
P270	Do not eat, drink, or smoke when using this product.
P280	Wear protective gloves.
P302 + P352	IF ON SKIN: Wash with plenty of soap and water.
P304 + P340	IF INHALED: Remove affected person into fresh air and keep at rest in a position comfortable for breathing.
P332 + P313	If skin irritation occurs: Get medical advice/ attention.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

Substance/ mixture Substance

Ingredient	CAS/Exempt No	Percent	Hazardous
Proprietary Ingredient	Proprietary	100	No

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice
Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled
Move person into fresh air. If cough or other symptoms develop, consult a physician.

In case of skin contact
Remove contaminated clothing including shoes and immediately wash affected area with plenty of soap and water. If irritation continues, consult a physician. Wash contaminated clothing and shoes before reuse.

In case of eye contact
Immediately flush eyes with plenty of water for two to three minutes. Remove any contact lenses and continue flushing for 15 minutes. If irritation continues, consult a physician.

If swallowed
Wash out mouth with water and keep at rest. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labeling (see Section 2.2) and/or in Section 11.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media
Use fire-extinguishing media appropriate for surrounding materials.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides, Sulfur oxides.

5.3 Advice for firefighters

As in any fire, wear full protective clothing and equipment.

5.4 Further information

No data available.

---

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid breathing vapours or mist. Evacuate personnel to safe areas.

6.2 Environmental precautions

Do not let product enter drains, if safe to do so.

6.3 Methods and materials for containment and cleanup

Construct temporary dikes of dirt or any appropriate readily available material to prevent spreading of the material. Cover with appropriate absorbent and sweep or shovel into an appropriate container.

6.4 Reference to other sections

For protective clothing, see Section 8. For disposal, see Section 13.

---

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of aerosols. Provide adequate exhaust ventilation at places where aerosols are formed. For precautions, see Section 2.2. Handle and use in a manner consistent with good industrial/manufacturing techniques and practices.

7.2 Conditions for safe storage

Keep container tightly closed in a dry, cool, and well-ventilated place.

7.3 Specific end uses(s)

Apart from the uses mentioned in Section 1.2, no other specific uses are stipulated.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters
No PELs, TLVs, or OELs for this product or its ingredients are listed in the current issue of ACGIH's Guide to Occupational Exposure Values, nor have they been determined by the manufacturer.

8.2 Exposure controls

Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

Personal protective equipment

Eye/face protection
Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU).

Skin protection
Handle with chemical-resistant gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body protection
Impervious clothing. The type of protective equipment must be selected according to the amount of dangerous substance at the specific workplace.

Control of environmental exposure
Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a)	Appearance	Form: Powder Color: White (PRE 1) : Yellow (PRE 2)
b)	Odor	Odorless
c)	Melting range	234 – 236.5°C – (lit.) (PRE 1) : >300°C (PRE 2)
d)	Freeze point	Not determined
e)	Density	1.230 g/cm^3 (PRE 1)
f)	Flash point	Not determined
g)	pH	5.5 – 6.5 at 10 g/L at 20°C (PRE 1) : 7.5 at 10g/L (PRE 2)
h)	Evaporation factor	Not determined
i)	Solubility	18.7 g/L at 16°C (PRE 1) : Soluble (PRE 2)
j)	Vapor pressure	15 mmHg at 89°C (PRE 1)
k)	Oxidizing properties	Not determined

l)	Vapor density	Not determined
m)	Viscosity	Not determined

9.2 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical stability

The product is stable under normal ambient conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Will not polymerize.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

None.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity – oral
(PRE 1) LD_{50} Oral – rat – male and female – 367.7 mg/kg
(OECD Test Guideline 401)

(PRE 2) LD_{50} Oral – rat – male and female – 12750 mg/kg
(OECD Test Guideline 401)

Acute toxicity – inhalation
(PRE 1) LC_{50} Inhalation – rat – male and female – 4.94 mg/L
(OECD Test Guideline 401)

Acute toxicity – dermal
(PRE 1) LD_{50} Inhalation – rat – male and female – > 2,000 mg/kg
(OECD Test Guideline 401)

Skin corrosion/irritation
Skin irritant 2 – H315 Causes skin irritation.

Serious eye damage/irritation
Eye irritant 2 – H319 May cause severe eye irritation.

Respiratory sensitization
Based on available data the classification criteria are not met.

Skin sensitization
Based on available data the classification criteria are not met.

Germ cell mutagenicity

Genotoxicity – in vitro
Based on available data the classification criteria are not met.

Genotoxicity- in vivo
Based on available data the classification criteria are not met.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible, or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

Reproductive toxicity – fertility
Based on available data the classification criteria are not met.

Reproductive toxicity – development
Based on available data the classification criteria are not met.

Specific target organ toxicity – single exposure
STOT SE 3 – H335 May cause respiratory irritation.

Specific target organ toxicity – repeated exposure
Based on available data the classification criteria are not met.

Aspiration hazard
Not anticipated to present an aspiration hazard, based on chemical structure.

Additional information
RTECS: EV64750000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

12.2 Persistence and degradability

Presumed to be persistent.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment are not available as chemical safety assessment not required/ not conducted.

12.6 Other adverse effects

No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product
Dispose of at a supervised appropriate waste disposal facility according to current applicable laws and regulations and product characteristics at time of disposal.

Contaminated packaging
Contaminated containers should be cleaned and disposed of in the same manner as the product in accordance with applicable regulations.

14. TRANSPORT INFORMATION

Pre 1 **DOT (US)**

UN-No	UN1544
Hazard Class	6.1
Packing Group	III

IMDG

UN-No	UN1544
Hazard Class	6.1
Packing Group	III

IATA

UN-No	UN1544
Hazard Class	6.1
Packing Group	III

15. REGULATORY INFORMATION

SARA 302 Components
SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards
Acute Health Hazard, Chronic Health Hazard

CERCLA (Comprehensive Response, Compensation, and Liability Act)
Not Applicable.

TSCA (Toxic Substance Control Act)
The components of this product are in compliance with the chemical notification requirements of TSCA.

16. OTHER INFORMATION

HMIS Rating

Health Hazard:	2
Chronic Health Hazard:	*
Flammability:	1
Physical Hazard:	1

NFPA Rating

Health Hazard:	2
Fire Hazard:	1
Reactivity Hazard:	1

MANUFACTURER DISCLAIMER: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses which infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Prepared by: **ProTechnics Environmental Compliance Department**

ProTechnics Division of Core Laboratories
6510 W. Sam Houston Parkway N.
Houston, Texas 77041

Date of creation: 04-Apr-2019

Contact information: 713-328-2320

Appendix D.2 May 2021 Safety Data Sheets

Appendix D.2 April 2021 Safety Data Sheets

SDS no. U028
Version 5
Revision date 08-Jun-2018
Supersedes Date: 03-Jun-2014

Safety Data Sheet
Gelling Agent U28 - 30% Active

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Gelling Agent U28 - 30% Active
Product code U028

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a gelling agent in oilfield applications

Uses advised against No information available

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Skin corrosion/irritation	Category 1 Subcategory 1A

Environmental hazards Not classified

Physical Hazards

Substances/mixtures corrosive to metal	Category 1

2.2 Label elements



Signal word
DANGER

Hazard Statements
H314 - Causes severe skin burns and eye damage
H290 - May be corrosive to metals

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves and eye/face protection
P301 + P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Supplementary precautionary statements
P234 - Keep only in original container
P264 - Wash face, hands and any exposed skin thoroughly after handling
P363 - Wash contaminated clothing before reuse
P310 - Immediately call a POISON CENTER or doctor/physician
P390 - Absorb spillage to prevent material damage
P220 - Keep/Store away from combustible materials

Sodium hydroxide

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Sodium hydroxide	215-185-5	1310-73-2	30

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Ingestion	Do NOT induce vomiting. Rinse mouth. Risk of product entering the lungs on vomiting after ingestion. Never give anything by mouth to an unconscious person. Immediate medical attention is required.
Skin contact	Promptly wash contaminated skin with soap or mild detergent and water. Promptly remove clothing if soaked through and wash as above. Burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Chemical burns must be treated by a physician.
Eye Contact	Get immediate medical attention. Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.

4.2. Most important symptoms and effects, both acute and delayed

General advice	Seek medical attention for all burns, regardless how minor they may seem. The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.
Symptoms	
Inhalation	Please see Section 11. Toxicological Information for further information.
Ingestion	Please see Section 11. Toxicological Information for further information.
Skin contact	Please see Section 11. Toxicological Information for further information.
Eye contact	Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Contact with metals may evolve flammable hydrogen gas.

Hazardous combustion products
Fire or high temperatures create: Heating or fire can release toxic gas.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 2R

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not get on skin or clothing. Wash thoroughly after handling. Do not breathe vapors or spray mist. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13).

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Do not get in eyes, on skin or on clothing. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store between 15-25 deg. C (59-77 deg. F) Avoid extreme temperatures Store away from incompatibles, Strong acids Halogenated compounds Metals
Storage class	Corrosive storage.
Packaging materials	High density polyethylene (HDPE) drum or can

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits Because this product is a liquid, the dust-related Workplace Exposure Limits for the components do not apply.

, Component Information

Chemical Name	Arabic	Australia	Egypt
Sodium hydroxide	Not determined	2 mg/m³ Peak	2 mg/m³ Ceiling
Chemical Name	**India**	**Indonesian**	**Japan**
Sodium hydroxide	2 mg/m³ Ceiling	2 mg/m³ Ceiling	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Sodium hydroxide	Not determined	2.0 mg/m³ STEL	2 mg/m³ Ceiling
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Sodium hydroxide	2 mg/m³ Ceiling	2 mg/m³ TWA	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Sodium hydroxide	2 mg/m³ TWA	Not determined	Not determined

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly fitting safety goggles / Face-shield

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Wear protective nitrile rubber gloves
Break through time >480 minutes
Glove thickness 0.35-0.4 mm
Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Respirator with a vapor filter (EN 141) Chemical respirator with inorganic vapour cartridge (Grey B). At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Odor	Odorless
Color	Colorless
Odor threshold	Not applicable

Property	Values	Remarks
pH	13.5	
pH @ dilution	No information available	
Melting / freezing point	8 °C / 46 °F	
Boiling point/range	115 °C / 239 °F	
Flash point		
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.3	@20 °C
Bulk density	No information available	
Relative density	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	Not applicable	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	75 mPa s	@ 20 °C
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

Corrosive.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid extreme temperatures. Store at ambient conditions.

10.5 Incompatible materials

Strong acids. Halogenated compounds. Metals. Gives off hydrogen by reaction with metals.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information Causes severe skin burns and eye damage.

Inhalation Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate.

Eye contact Causes burns. Causes serious eye damage.

Skin contact Corrosive. Causes burns.

Ingestion Can burn mouth, throat, and stomach.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hydroxide	No data available	1350 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Skin contact. Eye contact.

Routes of entry No route of entry noted.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
The product may affect the acidity (pH-factor) in water with risk of harmful effects to aquatic organisms.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Sodium hydroxide	= 45.4 mg/L LC50 Oncorhynchus mykiss 96 h	No information available	No information available

12.2 Persistence and degradability

This product is expected to be readily biodegradable.

12.3 Bioaccumulative potential

Does not bioaccumulate.

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of as special waste in compliance with local and national regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN1824
UN No. (IMDG/ANTAQ)	UN1824
UN No. (ICAO/ANAC)	UN1824

14.2. UN proper shipping name
SODIUM HYDROXIDE SOLUTION,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	8
IMDG/ANTAQ Hazard class	8
ICAO/ANAC Hazard class/division	8

14.4 Packing group

ADR/RID/ADN/ADG Packing group	PG II
IMDG/ANTAQ Packing group	PG II
ICAO/ANAC Packing group	PG II



14.5 Environmental hazard
No

14.6 Special precautions

Hazard identification no (ADR)	80
EmS (IMDG)	F-A, S-B

Emergency Action Code (EAC)	2R
Tunnel restriction code	(E)
Hazchem code ADG	2R

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Sodium hydroxide
Schedule 6
Schedule 5

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	03-Jun-2014
Revision date	08-Jun-2018
Version	5
This SDS has been revised in the following section(s)	1, 2, 8, 11, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	3
Flammability	0
Physical hazard	1
PPE	X

Disclaimer

The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. B499
Version 1
Revision date 10-Jun-2016
Supersedes date None

Safety Data Sheet
Natural Corrosion Inhibitor B499

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Natural Corrosion Inhibitor B499
Product code B499

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to (EC) No. 1272/2008

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary Statements - EU (§28, 1272/2008)

This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

-

Contains

2.3 Other data

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not Applicable

4. First aid measures

4.1 First-Aid Measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which shall not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Dust may form explosive mixture in air.

Hazardous combustion products
Fire or high temperatures create:, Carbon oxides (COx), Nitrogen oxides (NOx), Hydrogen cyanide (hydrocyanic acid), Thermal decomposition can lead to release of toxic and corrosive gases/vapors.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. Use non-sparking tools and equipment. Avoid dust formation. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Keep away from open flames, hot surfaces and sources of ignition.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid heat, flames and other sources of ignition.
Storage class	Chemical storage.
Packaging material	Use specially constructed containers only.

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits	NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure
Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed.

Personal protective equipment

Eye protection	Safety glasses with side-shields. Tightly fitting safety goggles.
Hand protection	Repeated or prolonged contact:, Use protective gloves made of:, Butyl, Nitrile, Frequent change is advisable.
Respiratory protection	No personal respiratory protective equipment normally required, In case of insufficient ventilation wear suitable respiratory equipment, Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181), At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.

Hygiene measures Wash hands before eating, drinking or smoking, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Flakes Powder
Odor	Odorless
Color	Off-white
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	No information available	
pH @ dilution		
Melting/freezing point	260-280 °C / 500-536 °F	
Boiling point/range	No information available	
Flash point	No information available	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not Applicable	
Flammability Limits in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.5 - 0.7	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Miscible with water.	
Solubility in other solvents	No information available	
Autoignition temperature	500 °C / 932 °F	
Decomposition temperature	400 C	

Kinematic viscosity	No information available
Dynamic viscosity	No information available
Log Pow	No information available

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Dust may form explosive mixture in air.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation. Avoid heat, flames and other sources of ignition.

10.5 Incompatible materials

No materials to be especially mentioned.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust in high concentration may cause irritation of respiratory system.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not Applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.
Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Skin contact. Inhalation. Eye contact.
Routes of entry	No route of entry noted.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified.
Aspiration hazard	Not Applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
No product level data available.

Toxicity to fish
No product level data available.

Toxicity to daphnia and other aquatic invertebrates
No product level data available.

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility in soil

Mobility
The product is miscible with water. May spread in water systems.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.
EWC Waste disposal No.	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used. The following Waste Codes are only suggestions: EWC waste disposal No: Waste Code: 16 03 06 - organic wastes other than those mentioned in 16 03 05 01 04 10 – dusty and powdery wastes other than those mentioned in 01 04 07,

14. Transport information

14.1 UN Number
Not regulated

14.2 Proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG Hazard class	Not regulated
ICAO Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG Packing group	Not regulated
ICAO Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions

Not Applicable

Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Australian Standard for the Uniform Scheduling of Drugs and Poisons
No Poisons Schedule number allocated

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG Code) for transport by road or rail.

International inventories

USA (TSCA)	Complies
European Union (EINECS and ELINCS)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel

Revision date	10-Jun-2016
Version	1
The following sections have been revised:	New issue.

Full text of H-Statements referred to under sections 2 and 3

This product is not classified as hazardous therefore no (H) hazard statements assigned.

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. F112
Version 3
Revision date 15-Aug-2018
Supersedes Date: 07-May-2018

Safety Data Sheet
Surfactant F112

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Surfactant F112
Product code F112

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Surfactant in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2

Environmental hazards

Chronic aquatic toxicity	Category 3

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements
P273 - Avoid release to the environment
P280 - Wear protective gloves and eye/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Supplementary precautionary statements
P337 + P313 - If eye irritation persists: Get medical advice/attention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse

Contains
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-

Dicoco dimethyl quaternary ammonium chloride

Propan-2-ol

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Inhalation of vapors in high concentration may cause irritation of respiratory system

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	500-077-5	31726-34-8	10-<20
Dicoco dimethyl quaternary ammonium chloride	263-087-6	61789-77-3	0.5-<1.0
Propan-2-ol	200-661-7	67-63-0	0.1-<0.25

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion If swallowed, call a poison control center or doctor immediately. Do NOT induce vomiting. If conscious, drink plenty of water.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention if irritation persists.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Extinguish with carbon dioxide, dry chemical, foam or waterspray.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors Carbon oxides (COx), Nitrogen oxides (NOx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 3Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13). After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Do not get in eyes, on skin or on clothing. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands before eating, drinking or smoking Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Avoid contact with: Strong oxidizing agents
Storage class	Chemical storage.

Packaging materials Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Component Information

Chemical Name	Arabic	Australia	Egypt
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA	500ppmSTEL 1230mg/m³STEL 400ppmTWA 983mg/m³TWA	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA
Chemical Name	**India**	**Indonesian**	**Japan**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	Not determined	400 ppm TWA 983 mg/m³ TWA 500 ppm STEL 1230 mg/m³ STEL	200 ppm ACL
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	10 mg/m³ MAC	1225 mg/m³ STEL 500 ppm STEL	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	400 ppm TWA 983 mg/m³ TWA	400 ppm TWA 980 mg/m³ TWA	50 mg/m³ STEL 10 mg/m³ TWA
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	400 ppm TWA	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment
Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly

	fitting safety goggles
Hand protection	Impervious gloves made of: Nitrile or Butyl Break through time >480 minutes Glove thickness 0.5 mm Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	No personal respiratory protective equipment normally required In case of insufficient ventilation wear suitable respiratory equipment Use respirator with organic vapor/acid gas protection (E, yellow) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odor	Alcohol
Color	Clear Yellow
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	9-11	
pH @ dilution	No information available	Not applicable
Melting / freezing point	5 °C / 41 °F	
Boiling point/range	~ 100 °C / 212 °F	
Flash point	> 93.3 °C / > 199.4 °F	PMCC
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.99 - 1.03 g/cm^3	@ 20 °C
Bulk density	No information available	
Relative density	~ 1.0	@ 20°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	5-50 mPa s	@ 16 °C
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	< 1
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of vapors in high concentration may cause irritation of respiratory system.
Eye contact	Causes serious eye irritation.
Skin contact	Causes skin irritation.
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Unknown acute toxicity	Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation

Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	LD50: 1250 mg/kg, rat, (based on data from similar substance)	LD50: > 2000 mg/kg, rat, (based on data from similar component)	No data available
Dicoco dimethyl quaternary ammonium chloride	= 960 mg/kg (Rat)	LD50 > 2930 mg/kg, rabbit	No data available
Propan-2-ol	= 1870 mg/kg (Rat)	= 4059 mg/kg (Rabbit)	= 72600 mg/m³ (Rat) 4 h

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Eye contact. Skin contact. Inhalation.

Routes of entry Eye contact. Skin contact.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

Harmful to aquatic life with long lasting effects

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	LC50 96h, Brachydanio rerio (zebrafish): > 100 mg/l (test based on similar component)	EC50, 72h: > 100 mg/kg (based on similar substance)	EC50, 48h, Daphnia magna (Water flea): > 100 mg/l (based on similar product)
Dicoco dimethyl quaternary ammonium chloride	No information available	No information available	EC50, 48h, Daphnia : 0.01 mg/l
Propan-2-ol	> 1400000 µg/L LC50 Lepomis macrochirus 96 h = 11130 mg/L LC50 Pimephales promelas 96 h = 9640 mg/L LC50 Pimephales promelas 96 h	> 1000 mg/L EC50 Desmodesmus subspicatus 96 h > 1000 mg/L EC50 Desmodesmus subspicatus 72 h	= 13299 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

Product is biodegradable.

Chemical Name	Persistence and degradability
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Readily biodegradable
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	Readily biodegradable

12.3 Bioaccumulative potential

Does not bioaccumulate.

Chemical Name	Bioaccumulation
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not likely to bioaccumulate
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	No bioaccumulation potential

12.4 Mobility

Mobility
Soluble in water.

Chemical Name	Mobility
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Miscible in water
Dicoco dimethyl quaternary ammonium chloride	Soluble in water
Propan-2-ol	Soluble in water

Mobility in soil
No information available.

Chemical Name	Mobility in soil
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	No information available
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	No information available

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable
Hazchem code ADG 3Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Does not comply
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	07-May-2018
Revision date	15-Aug-2018
Version	3
This SDS has been revised in the following section(s)	2, 12, 14, 16 There have been changes with regard to classification.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2
Flammability	1
Physical hazard	0
PPE	X

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This Document is Confidential and Proprietary. Unless Otherwise Marked, It is an Uncontrolled Copy.

Safety Data Sheet
Hydrochloric Acid 15% H15

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Hydrochloric Acid 15% H15
Product code H015
Norway Pr. no. 17101
Denmark Pr. no. 1088965

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as an acidizing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield UK PLC
Victory House, Churchill Court
Manor Royal, Crawley
West Sussex RH10 9LU
+ 47 51577424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

Denmark	Poison Control Hotline (DK): +45 82 12 12 12
Netherlands	National Poisons Information Centre (NL): +31 30 274 88 88 (NB: this service is only available to health professionals)
Norway	Poison information centre: +47 22 59 13 00

2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Health hazards

Skin corrosion/irritation	Category 1 Subcategory 1B
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Substances/mixtures corrosive to metal	Category 1

2.2 Label elements



Signal word
DANGER

Hazard statements
H314 - Causes severe skin burns and eye damage
H335 - May cause respiratory irritation
H290 - May be corrosive to metals

Precautionary Statements - EU (§28, 1272/2008)
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/ physician
P406 - Store in corrosive resistant/ . container with a resistant inner liner

Supplementary precautionary statements
P234 - Keep only in original container
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P362 - Take off contaminated clothing and wash before reuse
P390 - Absorb spillage to prevent material damage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/container in accordance with local regulations.

-

Contains
Hydrochloric acid

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to 67/548/EEC	Regulation (EC) No 1272/2008	REACH registration number
Hydrochloric acid	231-595-7	7647-01-0	15	-	Skin Corr. 1A (H314) STOT SE 3 (H335) Met. Corr.1 (H290) Note B	01-2119484862-27-xxxx

Comments
The product contains other ingredients which do not contribute to the overall classification.
Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

4. First aid measures

4.1 First Aid

Inhalation Move the exposed person to fresh air at once. If breathing is difficult, (trained personnel should) give oxygen. If not breathing, give artificial respiration. Seek medical attention at once.

Ingestion Do NOT induce vomiting. Get immediate medical attention. Rinse mouth. Risk of product entering the lungs on vomiting after ingestion. Never give anything by mouth to an unconscious person.

Skin contact Promptly wash contaminated skin with soap or mild detergent and water. Promptly remove clothing if soaked through and wash as above. Burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Chemical burns must be treated by a physician.

Eye contact Remove contact lenses. Immediately flush eyes with water for 15 minutes while holding eyelids open. Immediate medical attention is required.

4.2 Most important symptoms and effects, both acute and delayed

General advice Seek medical attention for all burns, regardless how minor they may seem. The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
The product itself does not burn, Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Contact with metals may evolve flammable hydrogen gas.

Hazardous combustion products
Fire or high temperatures create: Chlorine, chlorine oxides, hydrogen chloride.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not get on skin or clothing. Wash thoroughly after handling. Do not breathe vapours or spray mist. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so. Dyke far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13).

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure Do not eat, drink or smoke when using this product Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Use only in area provided with appropriate exhaust ventilation. Keep airborne concentrations below exposure limits. Keep away from heat.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Avoid excessive heat for prolonged periods of time. Store away from incompatibles, Strong oxidising agents Alkalis Metals
Storage class	Corrosive storage.
Packaging materials	Use specially constructed containers only

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Chemical Name	EU OEL - Third List	Austria	Australia	Denmark
Hydrochloric acid	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	Not determined	5 ppm Ceiling 8 mg/m³ Ceiling
Chemical Name	**Malaysia**	**France**	**Germany**	**Hungary**
Hydrochloric acid	5 ppm Ceiling 7.5 mg/m³ Ceiling	5ppmSTEL 7.6mg/m³STEL	2 ppm TWA 3.0 mg/m³ TWA	8mg/m³TWA 16mg/m³STEL
Chemical Name	**New Zealand**	**Italy**	**Netherlands**	**Norway**
Hydrochloric acid	5 ppm Ceiling 7.5 mg/m³ Ceiling	Not determined	8 mg/m³ GW	5 ppm Ceiling; 7 mg/m³ Ceiling
Chemical Name	**Poland**	**Portugal**	**Romania**	**Russia**
Hydrochloric acid	10 mg/m³ STEL NDSCh	10 ppm STEL VLE-CD	10ppmSTEL	Acute dangerous

	5 mg/m³ TWA NDS	15 mg/m³ STEL VLE-CD 5 ppm TWA indicative limit value 8 mg/m³ TWA indicative limit value	15mg/m³STEL 5ppmTWA 8mg/m³TWA	substance 5 mg/m³ MAC
Chemical Name	**Spain**	**Switzerland**	**Turkey**	**UK**
Hydrochloric acid	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA VLA-ED 7.6 mg/m³ TWA VLA-ED	4 ppm STEL 6 mg/m³ STEL 2 ppm TWA MAK 3.0 mg/m³ TWA MAK	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	5 ppm STEL aerosol mist and gas 8 mg/m³ STEL aerosol mist and gas 1 ppm TWA aerosol mist and gas 2 mg/m³ TWA aerosol mist and gas

Derived No Effect Level (DNEL)

Short term exposure local effects

Hydrochloric acid

Inhalation 15 mg/m³

Long term exposure local effects

Hydrochloric acid

Inhalation 8 mg/m³

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure

Ensure adequate ventilation. Provide mechanical general and/or local exhaust ventilation to prevent release of vapor or mist into work environment.

Personal protective equipment

Eye protection Eye protection must conform to standard EN 166. Chemical splash goggles and face shield.

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training
Use protective gloves made of: Butyl Rubber Nitrile Viton
Break through time >480 minutes
Glove thickness 0.5 mm
Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection No personal respiratory protective equipment normally required, In case of insufficient ventilation wear suitable respiratory equipment, Respirator with combination filter for vapour/particulate (EN 141), Type E/P2, At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.

Hygiene measures Wash hands before eating, drinking or smoking, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odour	Pungent
Colour	Colourless
Odour threshold	No information available

Property	**Values**	**Remarks**
pH	< 2	
pH @ dilution		
Melting / freezing point	< 0 °C / 32 °F	
Boiling point/range	~100 °C / 212 °F	
Flash point	Not applicable	
Evaporation rate	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapour pressure	31.33 hPa (@ 20°C)	
Vapour density	1.267	
Specific gravity	1.1	@ 16 °C
Bulk density	No information available	
Relative density	1.161 - 1.19 g/cm³	@ 20 °C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	1 mPa.s (@ 20 °C)	
log Pow	Not determined	

Explosive properties	Not applicable
Oxidising properties	None known

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Corrosive. Corrosive to Metals. Contact with metals may evolve flammable hydrogen gas.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerisation
Hazardous polymerisation does not occur.

10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5 Incompatible materials

Strong oxidising agents. Alkalis. Metals.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Vapours are corrosive. After 24-36 hours, injured persons may develop serious shortness of breath and lung oedema. Vapours irritate the respiratory system, and may cause coughing and difficulties in breathing.

Eye contact Causes serious eye damage.

Skin contact Causes severe skin burns.

Ingestion Ingestion causes burns of the upper digestive and respiratory tracts.

Unknown acute toxicity Not applicable.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrochloric acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Sensitisation This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	Inhalation. Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Category 3
Specific target organ toxicity - Repeated exposure	Not classified.
Target organ effects	Respiratory system.
Aspiration hazard	Not applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Large amounts will affect pH and harm aquatic organisms

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Hydrochloric acid	= 282 mg/L LC50 Gambusia affinis 96 h	No information available	No information available

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

12.4 Mobility in soil

Mobility
Soluble in water.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of as hazardous waste in compliance with local and national regulations.
Contaminated packaging	Empty containers should be transported/delivered using a registered waste carrier for local recycling or waste disposal.
EWC Waste Disposal No	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific Waste codes should be assigned by the user based on the application for which the product was used The following Waste Codes are only suggestions: EWC waste disposal No: 7131 Inorganic Acids 16 03 03 - inorganic wastes containing dangerous substances

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN 1789
UN No. (IMDG)	UN 1789
UN No. (ICAO)	UN 1789

14.2. UN proper shipping name
HYDROCHLORIC ACID SOLUTION 15%

14.3. Hazard class(es)

ADR/RID/ADN/ADG Hazard class	8
IMDG Hazard class	8
ICAO Hazard class/division	8

14.4 Packing group

ADR/RID/ADN/ADG Packing Group	III
IMDG Packing group	III

ICAO Packing group III



14.5 Environmental hazard
No

14.6 Special precautions

Hazard ID	80
EmS (IMDG)	F-A, S-B
Emergency Action Code (EAC)	2R
Tunnel restriction code	(E)

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Germany, Water Endangering Classes (VwVwS)	Hazardous to water/Class 1

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Hydrochloric acid
Schedule 6
Schedule 5

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

Dutch Mining Regulations: In accordance with Mining Regulations 9.2 and Chapter 4 of the Working Conditions Decree.

International inventories

USA, Toxic Substances Control Act inventory (TSCA)	Complies
European Union - EINECS and ELINCS	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Inventory - Japan - Existing and New Chemicals list	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korea (KECL)	Complies
Inventory - New Zealand - Inventory of Chemicals (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel
Supercedes date	19/Apr/2016
Revision date	31/Mar/2017
Version	3
This SDS has been revised in the following section(s)	All sections There have been changes with regard to classification.

Text of R phrases mentioned in Section 3
R34 - Causes burns
R37 - Irritating to respiratory system

Full text of H-Statements referred to under sections 2 and 3

H314 - Causes severe skin burns and eye damage
H335 - May cause respiratory irritation
H290 - May be corrosive to metals

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. J218
Version 5
Revision date 09-Aug-2018
Supersedes Date: 08-Sep-2017

Safety Data Sheet
Breaker J218

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Breaker J218
Product code J218

CAS No 7727-54-0
EC No 231-786-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

Croatia	01-23-48-342(for medical information) -Center for Poison

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Oxidizing Solids	Category 3

2.2 Label elements



Signal word
DANGER

Hazard Statements
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation
H272 - May intensify fire; oxidizer

Precautionary statements
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P280 - Wear protective gloves and eye/face protection

Supplementary precautionary statements
P220 - Keep away from clothing and other combustible materials
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P285 - In case of inadequate ventilation wear respiratory protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P330 - Rinse mouth
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/ container to an approved waste disposal plant
P410 - Protect from sunlight
P411 + P235 - Store at temperatures not exceeding 38 °C/ 100 °F. Keep cool
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P370 + P378 - In case of fire: Use water spray to extinguish

Contains
Diammonium peroxidisulphate

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Do not expose materials or their containers to moisture.

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Diammonium peroxidisulphate	231-786-5	7727-54-0	60-100

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get immediate medical attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Deluge with water. Other methods not effective.

Extinguishing media which must not be used for safety reasons
Dry chemical, carbon dioxide and other gas-filled extinguishers.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
May intensify fire; oxidizer.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors Sulfur oxides, Oxygen, Nitrogen oxides (NOx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 1Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Do not breathe dust. Avoid contact with the skin and the eyes.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Spilled oxidizer must be removed immediately and isolated for disposal. Isolated material must be monitored for signs of decomposition (fuming/smoking). If spilled material is wet, dissolve with large quantity of water. All disposals must be carried out at the earliest opportunity and in accordance with local /regional /national /international regulations. Take up mechanically and collect in suitable container for disposal. Use non-sparking tools and equipment. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety practice. Follow procedures for safe handling of oxidizers. Do not expose materials or their containers to moisture. Keep away from open flames, hot surfaces and sources of ignition. Avoid handling causing generation of dust. Avoid contact with skin and eyes. May produce an allergic reaction.

Hygiene Measures
Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing When using do not smoke, eat or drink.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Ensure adequate ventilation. Keep airborne concentrations below exposure limits.

Storage precautions Oxidizers must be stored separately from all other materials. Keep containers tightly closed in a dry, cool and well-ventilated place Protect from moisture Keep away from direct sunlight. Keep at a temperature not exceeding 110 °F /43 °C Keep away from open flames,

hot surfaces and sources of ignition Oxidizing material - Keep away from flammable and combustible materials. Store away from incompatible materials Oxidizing agents Reducing Agents Acids

Storage class Oxidiser storage.

Packaging materials Use specially constructed containers only.

Packaging materials to be avoided Containers made of MONEL, copper, brass, or iron.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits Control as an ACGIH particulate not otherwise specified (PNOS): 10 mg/m³ (Inhalable); 3 mg/m³ (Respirable) and an OSHA particulate not otherwise regulated (PNOR): 15 mg/m³ (Total); 5 mg/m³ (Respirable).

Component Information

Chemical Name	Arabic	Australia	Egypt
Diammonium peroxidisulphate	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Diammonium peroxidisulphate	Not determined	0.1 mg/m³ TWA	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Diammonium peroxidisulphate	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Diammonium peroxidisulphate	0.1 mg/m³ TWA	Not determined	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Diammonium peroxidisulphate	Not determined	Not determined	Not determined

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will

vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Tightly fitting safety goggles
Hand protection	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Do not wear rings, watches or anything similar which can retain the product and may give rise to skin conditions. Wear protective butyl rubber gloves Break through time >480 minutes Glove thickness 2 mm Frequent change is advisable
Respiratory protection	Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust) Effective dust mask. Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline
Odor	Odorless
Color	White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	4 - 5 @10 g/l	
Melting / freezing point	120 °C / 249 °F	
Boiling point/range	No information available	
Flash point		
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	

Vapor density	No information available	
Specific gravity	No information available	
Bulk density	1000 Kg/m³	
Relative density	1.26 g/cm³	@ 20°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	120 °C / 249 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	Strong oxidizer. Contact with other material may cause fire

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

This product is a strong oxidizer and reacts violently with combustibles and reducing agents.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid contamination. Avoid dust formation. Protect from moisture. Keep away from direct sunlight. Keep at a temperature not exceeding 110 °F /43 °C. Keep away from open flames, hot surfaces and sources of ignition. Oxidizing material - Keep away from flammable and combustible materials.

10.5 Incompatible materials

Do not mix oxidizers of any concentration with other oxidizing agents, reducing agents, flammable or combustible liquids or solids, acids, most metals and heavy metals, oxygen scavengers, corrosion inhibitors, surfactants, gelling agents, fluid-loss additives, cross linkers, solvents, foaming agents, clay control agents, or any chemical not specifically mentioned as being compatible with the specific oxidizer.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information May produce an allergic reaction.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation of respiratory tract.

Eye contact Causes serious eye irritation.

Skin contact Irritating to skin. May cause an allergic skin reaction.

Ingestion Harmful if swallowed.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diammonium peroxidisulphate	700-742 mg/kg (Rat)	> 2000 mg/kg (Rat)	No data available

Sensitization May cause sensitization by inhalation and skin contact.

Mutagenic effects This substance has no evidence of mutagenic properties.

Carcinogenicity This substance has no evidence of carcinogenic properties.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Inhalation. Skin contact. Eye contact.

Routes of entry Inhalation. Ingestion. Skin contact.

Specific target organ toxicity - Single exposure Category 3

Specific target organ toxicity - Repeated exposure Not classified.

Target organ effects Respiratory system.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Diammonium peroxidisulphate	= 76.3 mg/L LC50 Oncorhynchus mykiss 96 h	= 136 mg/l EC50 Phaenodactylum tricornutum 72h	= 120 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

Does not bioaccumulate.

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations.

Contaminated packaging Do not re-use empty containers. Dispose of contents/container to an approved waste disposal plant.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN 1444
UN No. (IMDG/ANTAQ)	UN 1444
UN No. (ICAO/ANAC)	UN 1444

14.2. UN proper shipping name
AMMONIUM PERSULFATE,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	5.1
IMDG/ANTAQ Hazard class	5.1
ICAO/ANAC Hazard class/division	5.1

14.4 Packing group

ADR/RID/ADN/ADG Packing group	PG III
IMDG/ANTAQ Packing group	PG III
ICAO/ANAC Packing group	PG III



14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions

Hazard identification no (ADR)	50
EmS (IMDG)	F-A, S-Q
Tunnel restriction code	(E)
Hazchem code ADG	1Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Not applicable

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Diammonium peroxidisulphate
Schedule 6

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	08-Sep-2017
Revision date	09-Aug-2018
Version	5
This SDS has been revised in the following section(s)	2, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2
Flammability	1
Physical hazard	2
PPE	X

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SDS no. J475
Version 4
Revision date 31-Aug-2017
Supersedes Date: 21-Aug-2017

Safety Data Sheet
EB-Clean* J475 Breaker

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name EB-Clean* J475 Breaker
Product code J475

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Oxidizing Solids	Category 3

2.2 Label elements



Signal word
DANGER

Hazard Statements
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation
H272 - May intensify fire; oxidizer

Precautionary statements
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P370 + P378 - In case of fire: Use water spray to extinguish
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P410 - Protect from sunlight
P411 - Store at temperatures not exceeding 38 °C/ 100 °F

Supplementary precautionary statements
P221 - Take any precaution to avoid mixing with combustibles
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P285 - In case of inadequate ventilation wear respiratory protection
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P330 - Rinse mouth
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Diammonium peroxodisulphate

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Diammonium peroxodisulphate	231-786-5	7727-54-0	60 - 100

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get immediate medical attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Deluge with water. Other methods not effective.

Extinguishing media which must not be used for safety reasons
Dry chemical, carbon dioxide and other gas-filled extinguishers.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
May intensify fire; oxidizer.

Hazardous combustion products
Heating or fire can release toxic gas Sulphur oxides, Oxygen, Nitrogen.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 1Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Do not breathe dust. Avoid contact with the skin and the eyes.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading.

Methods for cleaning up
Spilled oxidizer must be removed immediately and isolated for disposal. Isolated material must be monitored for signs of decomposition (fuming/smoking). If spilled material is wet, dissolve with large quantity of water. All disposals must be carried out at the earliest opportunity and in accordance with local /regional /national /international regulations. Take up mechanically and collect in suitable container for disposal. Take precautionary measures against static discharges. Use non-sparking tools and equipment. Avoid dust formation. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety practice. Follow procedures for safe handling of oxidizers. Do not expose materials or their containers to moisture. Keep

away from open flames, hot surfaces and sources of ignition. Avoid handling causing generation of dust. Avoid breathing dust; if exposed to high dust concentration, leave area immediately. Avoid contact with skin and eyes. Persons susceptible to allergic reactions should not handle this product.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Provide appropriate exhaust ventilation at places where dust is formed. Keep away from heat, sparks, and flame. Keep containers in cool areas out of direct sunlight and away from combustibles.

Storage precautions Oxidizers must be stored separately from all other materials. Keep containers tightly closed in a dry, cool and well-ventilated place Protect from moisture Keep away from direct sunlight. Keep at a temperature not exceeding 100°F /38 °C Keep away from open flames,

hot surfaces and sources of ignition Oxidizing material - Keep away from flammable and combustible materials. Store away from incompatibles, Strong reducing agents Strong bases Reducing Agents Heavy metals

Packaging materials Use specially constructed containers only. Coated (epoxy phenolic) steel drum or high density polyethylene (HDPE) can

Packaging materials to be avoided Containers made of MONEL, copper, brass, or iron.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.
No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Diammonium peroxodisulphate	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Diammonium peroxodisulphate	Not determined	0.1 mg/m^3 TWA	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Diammonium peroxodisulphate	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Diammonium peroxodisulphate	0.1 mg/m^3 TWA	Not determined	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Diammonium peroxodisulphate	Not determined	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Eye protection must conform to standard EN 166 Wear dust resistant safety goggles where there is a danger of eye contact.
Hand protection	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Do not wear rings, watches or anything similar which can retain the product and may give rise to skin conditions. Impervious gloves made of: polyvinyl alcohol or nitrile-butyl rubber gloves Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	Sweet
Color	White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	No information available	
pH @ dilution	6.5 - 8	@ 10g/l
Melting / freezing point	Decomposes	
Boiling point/range	No information available	
Flash point	> 93 °C / > 200 °F	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.8	@20 °C
Bulk density	1150 kg/m³	
Relative density	No information available	
Water solubility	10 - 20 g/l	@ 20 °C
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	120 °C/ 248 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	

log Pow	No information available
Explosive properties	No information available
Oxidizing properties	Oxidizer. Contact with other material may cause fire

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

This product is a strong oxidizer and reacts violently with combustibles and reducing agents.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Protect from moisture. Avoid dust formation. Avoid contamination. Keep away from direct sunlight.

10.5 Incompatible materials

Do not mix oxidizers of any concentration with other oxidizing agents, reducing agents, flammable or combustible liquids or solids, acids, most metals and heavy metals, oxygen scavengers, corrosion inhibitors, surfactants, gelling agents, fluid-loss additives, cross linkers, solvents, foaming agents, clay control agents, or any chemical not specifically mentioned as being compatible with the specific oxidizer.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information	May produce an allergic reaction.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation of respiratory tract. May cause drowsiness or dizziness.
Eye contact	Causes serious eye irritation.
Skin contact	Irritating to skin. May cause an allergic skin reaction.

Ingestion Harmful if swallowed.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diammonium peroxodisulphate	= 495 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	= 520 mg/L (Rat) 1 h

Sensitization May cause sensitization by inhalation and skin contact.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of Exposure Inhalation. Skin contact. Eye contact. Ingestion.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Category 3

Specific target organ toxicity - Repeated exposure Not classified.

Target organ effects Respiratory system.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Diammonium peroxodisulphate	= 323 mg/L LC50 Poecilia reticulata 96 h = 76.3 mg/L LC50 Oncorhynchus mykiss 96 h = 103 mg/L LC50 Lepomis macrochirus 96 h	No information available	= 120 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

Chemical Name	Persistence and degradability
Diammonium peroxodisulphate	Hydrolyzes

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

Chemical Name	Bioaccumulation
Diammonium peroxodisulphate	Product does not bioaccumulate due to reaction with water

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Chemical Name	Mobility
Diammonium peroxodisulphate	Easily soluble

Mobility in soil
No information available.

Chemical Name	Mobility in soil
Diammonium peroxodisulphate	Not expected to adsorb on soil

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of as special waste in compliance with local and national regulations.

Contaminated packaging Do not re-use empty containers. Dispose of contents/container to an approved waste disposal plant.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN1444
UN No. (IMDG/ANTAQ)	UN1444
UN No. (ICAO/ANAC)	UN1444

14.2. UN proper shipping name
AMMONIUM PERSULFATE,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	5.1
IMDG/ANTAQ Hazard class	5.1
ICAO/ANAC Hazard class/division	5.1

14.4 Packing group

ADR/RID/ADN/ADG Packing group	III
IMDG/ANTAQ Packing group	III
ICAO/ANAC Packing group	III



14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions

EmS (IMDG)	F-A, S-Q
Tunnel restriction code	E
Hazchem code ADG	1Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Diammonium peroxodisulphate
Schedule 6

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Anne Karin (Anka) Fosse
Supersedes Date:	21-Aug-2017
Revision date	31-Aug-2017
Version	4
This SDS has been revised in the following section(s)	8. EXPOSURE CONTROLS / PERSONAL PROTECTION No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2*
Flammability	1
Physical hazard	1
PPE	X

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SDS no. J580
Version 4
Revision date 07-Aug-2018
Supersedes Date: 21-Apr-2017

Safety Data Sheet
Water Gelling Agent J580

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Water Gelling Agent J580
Product code J580

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Suspended dust may present a dust explosion hazard

Australian statement of hazardous/dangerous nature

Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation — If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion — Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact — Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye Contact — Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice — The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation — Please see Section 11. Toxicological Information for further information.

Ingestion — Please see Section 11. Toxicological Information for further information.

Skin contact — Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Dust may form explosive mixture in air.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Extinguish all ignition sources. Avoid sparks, flames, heat and smoking.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Take precautionary measures against static discharges. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Material becomes slippery when wet. Use caution if wet.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits. Take precautionary measures against static discharges.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Keep away from open flames, hot surfaces and sources of ignition Protect from moisture Avoid contact with: Oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Mechanical ventilation or local exhaust ventilation is required. Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Safety glasses with side-shields Tightly fitting safety goggles
Hand protection	Wear gloves according to EN 374 to protect against skin effects from powders Use protective gloves made of: Neoprene Nitrile Rubber Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	Slight
Color	Light tan
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	5.5 - 7.5 (10g/L)	
Melting / freezing point	> 180 °C / 356 °F	
Boiling point/range	No information available	
Flash point	No information available	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.40 - 1.45	
Bulk density	800 kg/m³	
Relative density	No information available	
Water solubility	Dispersible	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	> 242 °C / 468 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties Suspended dust may present a dust explosion hazard
Oxidizing properties None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments

The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid dust formation. Protect from moisture.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.
Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.

Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	Inhalation.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	Not applicable.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

Listed on PLONOR list of OSPAR The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

Product is biodegradable.

12.3 Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4 Mobility

Mobility
Dispersible in water.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

No poisons schedule number allocated

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	21-Apr-2017
Revision date	07-Aug-2018
Version	4
This SDS has been revised in the following section(s)	1, 2, 7, 8, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	D

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SDS no. J604
Version 3
Revision date 22-Feb-2019
Supersedes Date: 30-Sep-2015

Safety Data Sheet
Crosslinker J604

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Crosslinker J604
Product code J604

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Specific target organ toxicity - Repeated exposure	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P330 - Rinse mouth

Supplementary precautionary statements
P314 - Get medical advice/attention if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Ethylene Glycol

Sodium Tetraborate Decahydrate

but-2-enedioic acid

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Ethylene Glycol	203-473-3	107-21-1	10-30
Sodium Tetraborate Decahydrate	215-540-4	1303-96-4	1-<5
but-2-enedioic acid	203-743-0	110-17-8	1-<3

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Seek medical attention if irritation occurs.

Skin contact Wash off immediately with soap and plenty of water. Remove contaminated clothing and shoes. Seek medical attention if irritation occurs.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and inhalation of vapors. Wash thoroughly after handling. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13). After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid spills and splashing during use. Do not breathe vapors or spray mist.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Do not eat, drink or smoke when using this product Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store in original container. Avoid heat, flames and other sources of ignition. Keep away from direct sunlight. Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits	No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Ethylene Glycol	Not determined	40ppmSTELvapour 104mg/m³STELvapour 10mg/m³TWAparticulate 20ppmTWAvapour 52mg/m³TWAvapour	39.4 ppm Ceiling 100 mg/m³ Ceiling
Sodium Tetraborate Decahydrate	Not determined	5mg/m³TWA 1mg/m³TWA	5 mg/m³ TWA
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Ethylene Glycol	Not determined	100 mg/m³ STEL	Not determined
Sodium Tetraborate Decahydrate	Not determined	5 mg/m³ TWA	Not determined
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Ethylene Glycol	5 mg/m³ MAC	125 mg/m³ TWA 50.0 ppm TWA 100 mg/m³ STEL	50 ppm Ceiling mist and vapour 127 mg/m³ Ceiling mist and vapour
Sodium Tetraborate Decahydrate	Not determined	Not determined	5 mg/m³ TWA
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Ethylene Glycol	39.4 ppm Ceiling aerosol 100 mg/m³ Ceiling aerosol	Not determined	10 mg/m³ STEL 5 mg/m³ TWA
Sodium Tetraborate Decahydrate	5 mg/m³ TWA	Not determined	2 mg/m³ MAC
but-2-enedioic acid	Not determined	Not determined	5 mg/m³ MAC
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Ethylene Glycol	Not determined	10 mg/m³ TWA 60 mg/m³ TWA 20 mg/m³ STEL 125 mg/m³ STEL	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA 52 mg/m³ TWA
Sodium Tetraborate Decahydrate	5 mg/m³ TWA	Not determined	Not determined
but-2-enedioic acid	Not determined	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Keep airborne concentrations below exposure limits Ensure adequate ventilation, especially in confined areas

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly fitting safety goggles Safety glasses with side-shields

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Wear chemical resistant gloves such as nitrile or neoprene. Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Respirator with a vapor filter (EN 141) Use respirator with organic vapor protection (A, brown) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Opaque
Odor	Odorless
Color	Beige or Milky white
Odor threshold	Not applicable

Property	Values	Remarks
pH	6.5 - 7.2	
pH @ dilution	No information available	
Melting / freezing point	No information available	
Boiling point/range	No information available	
Flash point	Does not flash	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.27 - 1.37	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Miscible with water.	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	None known.

9.2 Other information

Pour point	< -15 °C / < 5 °F
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Keep away from direct sunlight.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of vapors in high concentration may cause irritation of respiratory system. Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Eye contact May cause slight irritation.

Skin contact Prolonged contact may cause redness and irritation.

Ingestion Harmful if swallowed. May cause adverse kidney effects. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethylene Glycol	= 4700 mg/kg (Rat)	= 9530 µL/kg (Rabbit) = 10600 mg/kg (Rat)	No data available
Sodium Tetraborate Decahydrate	LD50 = 2660 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 2 mg/m³ (Rat) 4 h
but-2-enedioic acid	= 9300 mg/kg (Rat)	> 20000 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	Contains a known or suspected reproductive toxin.
Routes of Exposure	Inhalation. Skin contact. Eye contact. Ingestion.
Routes of entry	Inhalation. Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Category 2.
Target organ effects	Kidney.
Aspiration hazard	Not classified.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Ethylene Glycol	= 16000 mg/L LC50 Poecilia reticulata 96 h 40000 - 60000 mg/L LC50 Pimephales promelas 96 h = 40761 mg/L LC50 Oncorhynchus mykiss 96 h = 27540 mg/L LC50 Lepomis macrochirus 96 h 14 - 18 mL/L LC50 Oncorhynchus mykiss 96 h = 41000 mg/L LC50 Oncorhynchus mykiss 96 h	6500 - 13000 mg/L EC50 Pseudokirchneriella subcapitata 96 h	= 46300 mg/L EC50 Daphnia magna 48 h
Sodium Tetraborate Decahydrate	340 mg/L LC50 (Limanda limanda) = 96 h	2.6 - 21.8	1085 - 1402 mg/L LC50 (Daphnia magna) = 48 h
but-2-enedioic acid	= 245 mg/L LC50 Brachydanio rerio 48 h	= 41 mg/L EC50 Desmodesmus subspicatus 72 h	= 73.6 mg/L EC50 Daphnia magna 24 h 204 - 220 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility

Mobility
No information available.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

Not regulated

14.2. UN proper shipping name

The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated

IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Ethylene Glycol
Schedule 6
Schedule 5
Sodium Tetraborate Decahydrate
Schedule 4
Schedule 5

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Does not comply
Japan (ENCS)	Does not comply
China (IECSC)	Does not comply
Australia (AICS)	Complies
Korean (KECL)	Does not comply
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals)
Supersedes Date:	30-Sep-2015

Revision date	22-Feb-2019
Version	3
This SDS has been revised in the following section(s)	All sections Updated according to GHS/CLP.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2*
Flammability	1
Physical hazard	0
PPE	X

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SDS no. J693
Version 2
Revision date 04/Dec/2018
Supersedes date 13/Oct/2017

Safety Data Sheet
High Viscosity Friction Reducer J693

1. Identification of the Substance/Preparation and of the Company/Undertaking

1.1 Product identifier

Product name High Viscosity Friction Reducer J693

Product code J693

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications.

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Technology Corporation
110 Schlumberger Drive
Sugar Land, Texas 77478, USA
Telephone: 1-281-285-7873

Schlumberger Canada, Ltd.
200, 125 - 9th Avenue SE
Calgary, Alberta T2G 0P6, Canada
Telephone: 1-613-992-4624

E-mail address SDS@slb.com

Prepared by
Global Regulatory Compliance - Chemicals (GRC - Chemicals)

1.4 Emergency Telephone Number

Emergency telephone (24 Hour) Asia Pacific +65 3158 1074, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, USA +1 281 595 3518/+1 866 928 0789 , Canada +1 800 579 7421 , Argentina: +54 11 5984 3690, Brazil : 0800-720-8000 /0800-777-2323 (WGRA)

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS - Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary Statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

Hazards not otherwise classified
None known

Unknown acute toxicity Not applicable.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	CAS No	Weight-%
Distillates, petroleum, hydrotreated light	64742-47-8	15 - 40
Ammonium chloride	12125-02-9	1 - 5

Comments
The product contains other ingredients which do not contribute to the overall classification. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret

The viscosity of this product is high enough that it is not an aspiration risk and the H304 phrase does not apply.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors, Carbon oxides (COx), Nitrogen oxides (NOx), Ammonia.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and inhalation of vapors. Wash thoroughly after handling. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13). After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Avoid spills and splashing during use. If spilled, take caution, as material can cause surfaces to become very slippery.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. Do not eat, drink or smoke when using this product. Wash hands and face before breaks and immediately after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Ensure adequate ventilation. Keep airborne concentrations below exposure limits.

Storage precautions Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid heat, flames and other sources of ignition. Avoid contact with:. Strong oxidizing agents.

Packaging materials Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits **Oil mist (mineral) workplace exposure limits are currently under review by legislative authorities. This workplace exposure limit (WEL) standard is applicable to highly refined mineral oils and is provided as a guidance limit only LT. EXP = 5mg/m³ and ST. EXP = 10mg/m³.**

Chemical Name	ACGIH TLV	OSHA PEL	Argentina - Occupational Exposure Limits - TWAs (CMPs)	Brazil - Occupational Exposure Limits - TWAs (LTs)	Mexico - Occupational Exposure Limits - TWAs (LMPE-PPTs)
Distillates, petroleum, hydrotreated light	Not determined	Not determined	Not determined	Not determined	Not determined
Ammonium chloride	10 mg/m³	Not determined	10 mg/m³ TWA	Not determined	10 mg/m³ TWA VLE-PPT (fume)

IDLH (Immediately Dangerous to Life or Health)
This product contains substance(s) classified as Immediately Dangerous to Life or Health (IDLH) by the US National Institute for Occupational Safety and Health (NIOSH). The purpose of establishing an IDLH value is to ensure that the worker can escape from a given contaminated environment in the event of failure of the most protective respiratory protection equipment. In the event of failure of respiratory protection equipment every effort should be made to exit immediately.

Chemical Name	IDLH (Immediately Dangerous to Life or Health)
Distillates, petroleum, hydrotreated light 64742-47-8	-
Ammonium chloride 12125-02-9	-

8.2 Exposure controls

A risk assessment is recommended to be performed by a qualified and trained personnel to analyze the worksite and recommends the appropriate controls such as engineering controls, work practice controls, and administrative controls as primary means of reducing employee exposure. When there is a remaining hazards after applying the primary controls, Personal Protective Equipment (PPE) must be used.

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation. Keep airborne concentrations below exposure limits.

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against liquid splashes. Safety glasses with side-shields. Tightly fitting safety goggles.
Hand protection	Wear chemical resistant gloves such as nitrile or neoprene. Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory Protection	All respiratory protection equipment should be used within a comprehensive respiratory protection program that meets the requirements of 29 CFR 1910.134 (U.S. OSHA Respiratory Protection Standard) or local equivalent.If exposed to airborne mist/aerosol of this product, use an organic vapor cartridge with a P-95 pre-filter attached. In work environments containing oil mist/aerosol, use an organic vapor cartridge with a P-95 pre-filter attached.If exposed to vapors from this product, use a NIOSH/MSHA-approved respirator with an organic vapor cartridge.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product, Remove and wash contaminated clothing before re-use.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Color	White
Odor	Mild

Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	6.0 - 8.0	
pH @ dilution		
Melting / freezing point	< -6.67 °C/ 20 °F	
Boiling point/range	No information available	
Flash point	> 94 °C/ 201 °F	
Evaporation rate (BuAc =1)	< 1	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	No information available	
Lower flammability limit	No information available	
Vapor pressure	10 (<77 °C)	
Vapor density	No information available	
Specific gravity	1.045 - 1.055	
Bulk density	No information available	
Water solubility	Dispersible	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	
Explosive properties	No information available	
Oxidizing properties	No information available	

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of vapors in high concentration may cause irritation of respiratory system.

Eye contact May cause slight irritation.

Skin contact Prolonged contact may cause redness and irritation.

Ingestion Ingestion may cause stomach discomfort.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Distillates, petroleum, hydrotreated light	> 5000 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 5.2 mg/L (Rat) 4 h
Ammonium chloride	= 1650 mg/kg (Rat)	No data available	No data available

Chemical Name	IARC Group 1 or 2	ACGIH - Carcinogens	OSHA listed carcinogens	NTP
Distillates, petroleum, hydrotreated light	No data available	No data available	No data available	No data available
Ammonium chloride	No data available	No data available	No data available	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity Contains a known or suspected carcinogen.

Reproductive toxicity 2-Propenamid (impurity) may adversely affect the male reproductive system.

Developmental toxicity Component substance is listed on California Proposition 65 as a developmental hazard.

Routes of exposure Inhalation. Skin contact. Eye contact. Ingestion.

Routes of entry Inhalation. Skin contact. Eye contact.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard The viscosity of this product is high enough that it is not an aspiration risk and the H304 phrase does not apply.

12. Ecological Information

12.1 Toxicity

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Distillates, petroleum, hydrotreated light	= 45 mg/L LC50 Pimephales promelas 96 h = 2.2 mg/L LC50 Lepomis macrochirus 96 h = 2.4 mg/L LC50 Oncorhynchus mykiss 96 h	No information available	= 4720 mg/L LC50 Den-dronereides heteropoda 96 h
Ammonium chloride	= 109 mg/L (LC50; carp)	No information available	= 202 mg/L LC50 Daphnia magna 24 h

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility

Dispersible in water.

12.5 Results of PBT and vPvB assessment

This preparation contains no substance considered to be persistent, bioaccumulating nor toxic (PBT)
This preparation contains no substance considered to be very persistent nor very bioaccumulating (vPvB)

12.6 Other adverse effects.

None known.

13. Disposal Considerations

13.1 Waste treatment methods

Disposal Method Disposal should be made in accordance with federal, state and local regulations.

Contaminated packaging Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

UN No. (DOT) Not regulated

UN No. (MT/ANTT)	Not regulated
UN No. (TDG)	Not regulated
UN/ID No. (ADR/RID/ADN/ADG)	Not regulated
UN No. (IMDG/ANTAQ)	Not regulated
UN No. (ICAO/ANAC)	Not regulated
UN No. (DPC)	Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

DOT Hazard class	Not regulated
ANTT Hazard class	Not regulated
TDG Hazard class	Not regulated
ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated
DPC Hazard class	Not regulated

14.4 Packing group

DOT Packing group	Not regulated
ANTT Packing group	Not regulated
TDG Packing group	Not regulated
ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated
DPC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant	No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Does not comply
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

Europe - REACH
All products supplied from the European Economic Area (EEA) are compliant with the REACH Regulation EC 1907/2006.For

products supplied from the EEA, Schlumberger and/or its suppliers have pre-registered and is registering all of the substances that it and/or its suppliers manufactures in or imports into the EEA that are subject to Title II of the REACH Regulation. All products supplied from outside the EEA are subject to REACH only if imported into the EEA. The importer of the products must comply with REACH for each imported substance. Contact REACH@slb.com for REACH information.

IMPORTS, Canada
No import volume restrictions.

U.S. Federal and State Regulations

SARA 311/312 Hazard Categories
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications. Under the amended regulations at 40 CFR 370, EPCRA 311/312 Tier II reporting for the 2017 calendar year will need to be consistent with updated hazard classifications.

Chemical Name	SARA 302 / TPQs	SARA 313	CERCLA RQ
Distillates, petroleum, hydrotreated light	N/A	N/A	N/A
Ammonium chloride	N/A	N/A	5000 lb final RQ 2270 kg final RQ

California Proposition 65

WARNING



This product can expose you to chemicals including those listed below, which is [are] known to the State of California to cause cancer, birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov

Chemical Name	California Proposition 65
2-Propenamid (impurity) 79-06-1	developmental toxicity male reproductive toxicity carcinogen

16. Other Information

Supersedes date	13/Oct/2017
Revision date	04/Dec/2018
Version	2
This SDS has been revised in the following section(s)	1, 3, 5, 9, 10, 15, 16. Prepared in accordance with OSHA HAZCOM 2012. Prepared in accordance with WHMIS 2015

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	B

N/A - Not Applicable, N/D - Not Determined.

Disclaimer

The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

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SDS no. L065
Version 4
Revision date 18-Oct-2016
Supersedes date 11-Dec-2014

Safety Data Sheet
Scale Inhibitor L065

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Scale Inhibitor L065
Product code L065

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Scale Inhibitor. Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to (EC) No. 1272/2008

Health hazards

Acute oral toxicity	Category 4
Specific target organ toxicity (repeated exposure)	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard statements
H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with local regulations.

Supplementary precautionary statements
P314 - Get medical advice/attention if you feel unwell

-

Contains
Ethylene glycol

Calcium Chloride

2,2''-oxydiethanol (impurity)

Sodium hydroxide (impurity)

2.3 Other data

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

Not Applicable

3.2 Mixtures

Component	EC-No.	CAS-No	Weight % - range	Classification (67/548)	Classification (Reg. 1272/2008)	REACH registration number
Ethylene glycol	203-473-3	107-21-1	10-30	Xn; R48/22	Acute Tox. 4 (H302)	No data available

					STOT RE. 2(H373)	
Calcium Chloride	233-140-8	10043-52-4	1 - 5	Xi; R36	Eye Irrit. 2 (H319)	No data available
2,2''-oxydiethanol (impurity)	203-872-2	111-46-6	0.1 - 1.0	Xn; R22, R48/22	Acute Tox. 4 (H302) STOT RE. 2 (H373)	01-2119457857-21-xxxx
Sodium hydroxide (impurity)	215-185-5	1310-73-2	<1	C;R35	Skin Corr. 1A (H314)	No data available

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First aid measures

4.1 First-Aid Measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which shall not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid extreme temperatures. Avoid heat, flames and other sources of ignition. Store away from incompatibles, Strong oxidizing agents

Storage class Chemical storage.

Packaging material Use specially constructed containers only.

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits No biological limit allocated

Component	EU OEL	Austria	Australia	Denmark
Ethylene glycol	40 ppm STEL 104 mg/m³ STEL 20 ppm TWA 52 mg/m³ TWA Possibility of significant uptake through the skin	20 ppm STEL 52 mg/m³ STEL 10 ppm TWA 26 mg/m³ TWA	40ppmSTELvapour 104mg/m³STELvapour 10mg/m³TWAparticulate 20ppmTWAvapour 52mg/m³TWAvapour skin notation	10 ppm TWA 26 mg/m³ TWA 10 mg/m³ TWA Potential for cutaneous absorption
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	Not determined	40 ppm STEL 176 mg/m³ STEL 10 ppm TWA 44 mg/m³ TWA	23ppmTWA 100mg/m³TWA	2.5 ppm TWA 11 mg/m³ TWA
Sodium hydroxide (impurity)	Not determined	4 mg/m³ STEL inhalable fraction 2 mg/m³ TWA inhalable fraction	Not determined	2 mg/m³ Ceiling

Component	Malaysia	France	Germany	Hungary
Ethylene glycol	39.4 ppm Ceiling aerosol 100 mg/m³ Ceiling aerosol	40ppmSTEL 104mg/m³STEL 20 ppmTWA 52 mg/m³TWA	10 ppm TWA 26 mg/m³ TWA	52mg/m³TWA 104mg/m³STEL
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	Not determined	Not determined	10 ppm TWA 44 mg/m³ TWA	Not determined
Sodium hydroxide (impurity)	2 mg/m³ Ceiling	2 mg/m³TWA	Not determined	2mg/m³TWA 2mg/m³STEL

Component	New Zealand	Italy	Netherlands	Norway
Ethylene glycol	50 ppm Ceiling mist and vapour 127 mg/m³ Ceiling mist and vapour	Not determined	104mg/m³STEL 52 mg/m³ 10 mg/m³	20 mg/m³ TWA dust 52 ppm TWA total dust and vapor 52 mg/m³ TWA 52 mg/m³ STEL dust 20 ppm STEL Skin
Calcium Chloride	Not Determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	23 ppm TWA 101 mg/m³ TWA	Not determined	Not determined	Not determined
Sodium hydroxide (impurity)	2 mg/m³ Ceiling	Not determined	Not determined	2 mg/m³ Ceiling

Component	Poland	Portugal	Romania	Russia
Ethylene glycol	50 mg/m³ STEL NDSCh 15 mg/m³ TWA NDS	Skin 40 ppm STEL VLE-CD 104 mg/m³ STEL VLE-CD 20 ppm TWA indicative limit value 52 mg/m³ TWA indicative limit value	40ppmSTEL 104mg/m³STEL 20ppmTWA 52mg/m³TWA	10 mg/m³ STEL 2308 aerosol and vapor 5 mg/m³ TWA 2308
Calcium Chloride	Not determined	Not determined	Not determined	2 mg/m³ MAC Skin
2,2"-oxydiethanol (impurity)	10 mg/m³ TWA NDS	Not determined	184ppmSTEL 800mg/m³STEL 115ppmTWA	10 mg/m³ MAC (aerosol and vapor)

			500mg/m³TWA	
Sodium hydroxide (impurity)	1 mg/m³ STEL NDSCh 0.5 mg/m³ TWA NDS	Not determined	Not determined	Not determined
Component	**Spain**	**Switzerland**	**Turkey**	**UK**
Ethylene glycol	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA VLA-ED 52 mg/m³ TWA VLA-ED	20 ppm STEL 52 mg/m³ STEL Skin 10 ppm TWA MAK 26 mg/m³ TWA MAK	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA 52 mg/m³ TWA	40 ppm STEL vapour 104 mg/m³ STEL vapour 30 mg/m³ STEL calculated particulate Skin 10 mg/m³ TWA particulates 20 ppm TWA vapour 52 mg/m³ TWA vapour
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2''-oxydiethanol (impurity)	Not determined	40 ppm STEL (KZW): 176 mg/m³ STEL (KZW)	Not determined	69 ppm STEL calculated 303 mg/m³ STEL calculated 23 ppm TWA 101 mg/m³ TWA
Sodium hydroxide (impurity)	2 mg/m³ STEL	2 mg/m³ STEL inhalable dust 2 mg/m³ TWA MAK	Not determined	2 mg/m³ STEL

Derived No Effect Level (DNEL)

Long term exposure systemic effects

2,2''-oxydiethanol (impurity)

Dermal	106 mg/kg bw/day
Inhalation	60 mg/m³

Predicted No Effect Concentration (PNEC)

2,2''-oxydiethanol (impurity)

Fresh water	10 mg/l
Sea water	1 mg/l
Fresh water sediment	20.9 mg/kg sediment dw
Sea sediment	2.09 mg/kg sediment dw
Soil	1.53 mg/kg soil dw
Impact on sewage treatment	199.5 mg/L
Intermittent release	10 mg/l

Sodium hydroxide (impurity)

Impact on sewage treatment	1503

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure
Ensure adequate ventilation. Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Tightly fitting safety goggles. Safety glasses with side-shields.
Hand protection	Use protective gloves made of:, polyvinyl alcohol or nitrile-butyl rubber gloves, Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment, Respirator with combination filter for vapour/particulate (EN 141), At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at

the work place.

Hygiene measures Wash hands before breaks and immediately after handling the product, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odor	Mild
Color	Pale yellow
Odor threshold	Not applicable

Property	Values	Remarks
pH	7.8 - 8.8	
pH @ dilution		
Melting/freezing point	-50 °C / -58 °F	
Boiling point/range	100 °C / 212 °F	
Flash point	> 100 °C / 212 °F	PMCC
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not Applicable	
Flammability Limits in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	7 kPa	@ 20 °C
Vapor density	No information available	
Specific gravity	1.2	@15.6 °C
Bulk density	No information available	
Relative density	1.2	@ 15.6°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	5 mm2/s	@ 40 °C
Dynamic viscosity	6 mPa s	@ 38 °C
Log Pow	No information available	

Explosive properties	Not Applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid extreme temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of vapors in high concentration may cause irritation of respiratory system.

Eye contact May cause slight irritation.

Skin contact Prolonged contact may cause redness and irritation. Components of the product may be absorbed into the body through the skin.

Ingestion Harmful if swallowed. May cause adverse cardiac effects, blood disturbances, and metabolic acidosis. May cause damage to organs through prolonged or repeated exposure.

Unknown acute toxicity Not Applicable.

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethylene glycol	= 4700 mg/kg (Rat)	= 9530 µL/kg (Rabbit) = 10600 mg/kg (Rat)	No data available
Calcium Chloride	= 1000 mg/kg (Rat)	= 2630 mg/kg (Rat)	No data available
2,2"-oxydiethanol (impurity)	= 12565 mg/kg (Rat)	= 11890 mg/kg (Rabbit)	No data available
Sodium hydroxide (impurity)	No data available	= 1350 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Skin contact. Ingestion.
Routes of entry	Ingestion. Skin contact. Skin absorption.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Category 2.
Target organ effects	Kidney.
Aspiration hazard	Not Applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

Component	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Ethylene glycol	= 41000 mg/L LC50 Oncorhynchus mykiss 96 h 14 - 18 mL/L LC50 Oncorhynchus mykiss 96 h = 27540 mg/L LC50 Lepomis macrochirus 96 h = 40761 mg/L LC50 Oncorhynchus mykiss 96 h 40000 - 60000 mg/L LC50 Pimephales promelas 96 h = 16000 mg/L LC50 Poecilia reticulata 96 h	6500 - 13000 mg/L EC50 Pseudokirchneriella subcapitata 96 h	= 46300 mg/L EC50 Daphnia magna 48 h
Calcium Chloride	= 10650 mg/L LC50 Lepomis macrochirus 96 h	No information available	= 2400 mg/L LC50 Daphnia magna 48 h
2,2''-oxydiethanol (impurity)	= 75200 mg/L LC50 Pimephales promelas 96 h	No information available	= 84000 mg/L EC50 Daphnia magna 48 h
Sodium hydroxide (impurity)	= 45.4 mg/L LC50 Oncorhynchus mykiss 96 h	No information available	No information available

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility in soil

Mobility
The product is water soluble, and may spread in water systems.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.
EWC Waste disposal No.	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used. The following Waste Codes are only suggestions: EWC waste disposal No: 16 05 08 - discarded organic chemicals consisting of or containing dangerous substances.

14. Transport information

14.1 UN Number
Not regulated

14.2 Proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG Hazard class	Not regulated
ICAO Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG Packing group	Not regulated
ICAO Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Ethylene glycol
Schedule 6
Schedule 5
2,2''-oxydiethanol (impurity)
Schedule 6
Schedule 5
Sodium hydroxide (impurity)
Schedule 6
Schedule 5

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG Code) for transport by road or rail.

International inventories

USA (TSCA)	Complies
European Union (EINECS and ELINCS)	Does not Comply
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Does not Comply

China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Does not Comply
New Zealand (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel
Supersedes date	11-Dec-2014
Revision date	18-Oct-2016
Version	4
The following sections have been revised:	All sections, There have been changes with regard to classification.

Text of R phrases mentioned in Section 3
R22 - Harmful if swallowed
R35 - Causes severe burns
R36 - Irritating to eyes

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure
H314 - Causes severe skin burns and eye damage
H319 - Causes serious eye irritation

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. L071
Version 4
Revision date 31-Jul-2017
Supersedes Date: 02-Aug-2016

Safety Data Sheet
L071 Temporary Clay Stabilizer

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name L071 Temporary Clay Stabilizer
Product code L071

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Clay control agent in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

May cause slight irritation

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if symptoms occur.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Fire or high temperatures create: Thermal decomposition can lead to release of irritating gases and vapors, Nitrogen oxides (NOx), Carbon oxides (COx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Keep people away from and upwind of spill/leak. If spilled, take caution, as material can cause surfaces to become very slippery.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid breathing vapors or mists. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits	The product does not contain any hazardous materials with occupational exposure limits established.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required. See section 7 for more information

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against liquid splashes Safety glasses with side-shields
Hand protection	Wear gloves according to EN 374 resistant to the solvent(s) in use Impervious gloves made of: Nitrile Break through time >480 minutes Glove thickness 0.4 mm or PVC disposable gloves Break through time >480 minutes Glove thickness 0.7 mm Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Use respirator with

organic vapor protection (A, brown)

Skin and body protection Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Odor	Mild amine
Color	Clear - Blue
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	6.5 - 9.5	
pH @ dilution	No information available	Not applicable
Melting / freezing point	No information available	
Boiling point/range	125 °C / 257 °F	
Flash point	> 98 °C / 208.4 °F	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.99 - 1.20	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available

Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	May cause irritation of respiratory tract.
Eye contact	May cause slight irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Ingestion. Skin contact. Eye contact.
Routes of entry	Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	Not classified.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

Product is biodegradable.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility

Mobility
Soluble in water.

Mobility in soil
After release, adsorbs onto soil.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	02-Aug-2016
Revision date	31-Jul-2017
Version	4
This SDS has been revised in the following section(s)	1, 2, 3, 5, 7, 8, 9, 11, 15, 16 Updated according to GHS/CLP. No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

Training Advice
It is a good industrial hygiene practice to minimize skin contact

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	B

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SDS no. M003
Version 5
Revision date 18-Sep-2018
Supersedes Date: 10-Apr-2017

Safety Data Sheet
Soda Ash M3

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Soda Ash M3
Product code M003

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Buffer in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Serious eye damage/eye irritation	Category 2A

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H319 - Causes serious eye irritation

Precautionary statements
P264 - Wash face, hands and any exposed skin thoroughly after handling
P280 - Wear protective gloves and eye/face protection
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Sodium carbonate

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Sodium carbonate	207-838-8	497-19-8	60-100

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Seek medical attention if irritation occurs.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention immediately if symptoms occur.

Eye Contact Remove contact lenses, if worn. Promptly wash eyes with lots of water while lifting eye lids. Continue to rinse for at least 15 minutes. Seek medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Avoid dust formation.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Ensure adequate ventilation. Keep airborne concentrations below exposure limits.

Storage precautions Keep containers tightly closed in a dry, cool and well-ventilated place Protect from moisture Avoid contact with water and moist air - product is hygroscopic. Store away from incompatibles, Powdered aluminum Strong acids

Storage class Chemical storage.

Packaging materials Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Component Information

Chemical Name	Arabic	Australia	Egypt
Sodium carbonate	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Sodium carbonate	Not determined	Not determined	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Sodium carbonate	2 mg/m³ MAC	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Sodium carbonate	Not determined	Not determined	Skin notation Skin
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Sodium carbonate	Not determined	Not determined	Not determined

Notes

No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Tightly fitting safety goggles
Hand protection	Wear gloves according to EN 374 to protect against skin effects from powders Impervious gloves made of: Nitrile PVA Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	Odorless
Color	White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	11	
pH @ dilution	No information available	
Melting / freezing point	851 °C / 1564 °F	
Boiling point/range	Not applicable	
Flash point	Not applicable	
Evaporation rate (BuAc =1)	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	

Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	2.5	@20 °C
Bulk density	No information available	
Relative density	2.53	@ 20°C.
Water solubility	212.5g/L	@ 20 °C
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	>400°C/ 752°F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

Decomposes by reaction with strong acids.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Protect from moisture. Avoid contact with water and moist air - product is hygroscopic.

10.5 Incompatible materials

Powdered aluminum. Strong acids.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and

cough.

Eye contact Causes serious eye irritation. May cause pain, redness, discomfort.

Skin contact May cause skin irritation and/or dermatitis.

Ingestion Ingestion may cause stomach discomfort.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium carbonate	= 4090 mg/kg (Rat)	No data available	= 2300 mg/m³ (Rat) 2 h

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Skin contact. Eye contact. Inhalation.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Large amounts will affect pH and harm aquatic organisms

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Sodium carbonate	310 - 1220 mg/L LC50 Pimephales promelas 96 h = 300 mg/L LC50 Lepomis macrochirus 96 h	= 242 mg/L EC50 Nitzschia 120 h	= 265 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies

New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	10-Apr-2017
Revision date	18-Sep-2018
Version	5
This SDS has been revised in the following section(s)	1, 2, 7, 8, 15, 16 Updated according to GHS/CLP. No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	E

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Safety Data Sheet
Myacide® GA 25

1. Identification

Product identifier used on the label

Myacide® GA 25

Recommended use of the chemical and restriction on use
Recommended use*: Approved only for uses listed on the FIFRA label.

* The “Recommended use” identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:
BASF CORPORATION
100 Park Avenue
Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Substance number:	145849
EPA Registration number:	33753-26
Molecular formula:	CHO(CH2)3CHO
Chemical family:	dialdehydes, aqueous solution
Synonyms:	GLUTARALDEHYDE

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

Acute Tox.	4 (oral)	Acute toxicity
Acute Tox.	4 (Inhalation - mist)	Acute toxicity
Skin Corr./Irrit.	1B	Skin corrosion/irritation
Eye Dam./Irrit.	1	Serious eye damage/eye irritation
Resp. Sens.	1	Respiratory sensitization

Skin Sens.	1A	Skin sensitization
STOT SE	3 (irritating to respiratory system)	Specific target organ toxicity — single exposure
Aquatic Chronic	2	Hazardous to the aquatic environment - chronic
Aquatic Acute	1	Hazardous to the aquatic environment - acute

Label elements

Pictogram:



Signal Word:
Danger

Hazard Statement:

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H314	Causes severe skin burns and eye damage.
H302 + H332	Harmful if swallowed or if inhaled
H411	Toxic to aquatic life with long lasting effects.
H400	Very toxic to aquatic life.

Precautionary Statements (Prevention):

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P271	Use only outdoors or in a well-ventilated area.
P260	Do not breathe dust/mist/vapours.
P273	Avoid release to the environment.
P284	In case of inadequate ventilation wear respiratory protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P270	Do not eat, drink or smoke when using this product.
P264	Wash with plenty of water and soap thoroughly after handling.

Precautionary Statements (Response):

P310	Immediately call a POISON CENTER or doctor/physician.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.

Precautionary Statements (Storage):

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Precautionary Statements (Disposal):

P501	Dispose of contents/container in accordance with local regulations.

Hazards not otherwise classified

No specific dangers known, if the regulations/notes for storage and handling are considered.

Labeling of special preparations (GHS):
Corrosive to the respiratory tract.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

CAS Number	Weight %	Chemical name
111-30-8	>= 20.0 - < 50.0%	glutaral
67-56-1	>= 0.0 - < 0.3%	Methanol

4. First-Aid Measures

Description of first aid measures

General advice:
Immediately remove contaminated clothing. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). First aid personnel should pay attention to their own safety.

If inhaled:
Keep patient calm, remove to fresh air, seek medical attention.

If on skin:
Remove contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Seek medical attention. Consult a skin specialist.

If in eyes:
Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

If swallowed:
Immediately rinse mouth and then drink plenty of water, do not induce vomiting, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Further symptoms and / or effects are not known so far
Hazards: No applicable information available.

Indication of any immediate medical attention and special treatment needed

Note to physician

Treatment:	Treat according to symptoms (decontamination, vital functions), no known specific antidote, administer corticosteroid dose aerosol to prevent pulmonary odema.

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:
water spray, dry powder, foam

Special hazards arising from the substance or mixture

Hazards during fire-fighting:
harmful vapours
Evolution of fumes/fog. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Protective equipment for fire-fighting:
Wear a self-contained breathing apparatus in confined areas or when exposed to combustion products.

Further information:
Contaminated extinguishing water must be disposed of in accordance with official regulations.

Impact Sensitivity:

Impact Weight:	10 kg
Height of Fall:	0.4 m
Method:	Explosive properties
Remarks:	Substance/product is not impact sensitve at room temperature.

6. Accidental release measures

Further accidental release measures:
Pack in tightly closed containers for disposal.

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Pick up with absorbent material (e.g. sand, sawdust, general-purpose binder).
Dispose of absorbed material in accordance with regulations.
For large amounts: Pump off product.
Spills should be contained, solidified, and placed in suitable containers for disposal.

7. Handling and Storage

Precautions for safe handling

No special measures necessary provided product is used correctly.

Protection against fire and explosion:
No special precautions necessary.

Conditions for safe storage, including any incompatibilities

Segregate from foods and animal feeds.

Further information on storage conditions: Keep container tightly closed and in a cool place. Store protected against freezing.

8. Exposure Controls/Personal Protection

Users of a pesticidal product should refer to the product label for personal protective equipment requirements.

Components with occupational exposure limits

Methanol	OSHA PEL	PEL 200 ppm 260 mg/m3 ; TWA value 200 ppm 260 mg/m3 ; SKIN_FINAL ; The substance can be absorbed through the skin. STEL value 250 ppm 325 mg/m3 ;
	ACGIH TLV	TWA value 200 ppm ; STEL value 250 ppm ; Skin Designation ; The substance can be absorbed through the skin.
glutaral	OSHA PEL	CLV 0.2 ppm 0.8 mg/m3 ;
	ACGIH TLV	CLV 0.05 ppm ;

Advice on system design:
Provide local exhaust ventilation to control vapours/mists.

Personal protective equipment

RECOMMENDATIONS FOR MANUFACTURING, COMMERCIAL BLENDING, AND PACKAGING WORKERS:

Respiratory protection:
Wear respiratory protection if ventilation is inadequate. Respiratory protection in case of vapour/aerosol release. Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator.

Hand protection:
Wear chemical resistant protective gloves.

Eye protection:
Tightly fitting safety goggles (chemical goggles) and face shield.

Body protection:
Body protection must be chosen based on level of activity and exposure., Protective coverall and/or impermeable apron and boots as necessary.

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Keep away from food, drink and animal feeding stuffs. Avoid contact with skin and eyes. Remove contaminated clothing. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Form:	liquid
Odour:	characteristic

Odour threshold:	No applicable information available.	
Colour:	yellow	
pH value:	5.9 (0.5 %(m), 23 °C)	
Freezing point:	approx. -5 °C (1 ATM)	
Boiling point:	> 100 °C (1 ATM)	
Sublimation point:	No applicable information available.	
Flash point:	not applicable	
Flammability:	No applicable information available.	
Lower explosion limit:	No applicable information available.	
Upper explosion limit:	No applicable information available.	
Autoignition:	> 275 °C	(DIN 51794)
Vapour pressure:	approx. 17.5 mmHg (20 °C) The product has not been tested. The statement has been derived from the properties of the individual components.	
Density:	1.06 g/cm3 (20 °C)	
Relative density:	1.06 (20 °C)	
Vapour density:	No applicable information available.	
Partitioning coefficient n-octanol/water (log Pow):	No applicable information available.	
Thermal decomposition:	No decomposition if correctly stored and handled.	
Viscosity, dynamic:	No applicable information available.	
Viscosity, kinematic:	No applicable information available.	
Solubility in water:	soluble	
Solubility (quantitative):	No applicable information available.	
Solubility (qualitative):	No applicable information available.	
Molar mass:	100 g/mol	
Evaporation rate:	Value can be approximated from Henry's Law Constant or vapor pressure.	
Other Information:	If necessary, information on other physical and chemical parameters is indicated in this section.	

10. Stability and Reactivity

Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals:
No corrosive effect on metal.

Formation of flammable gases:	Remarks:	Forms no flammable gases in the presence of water.

Chemical stability
The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions
The product is chemically stable.

Conditions to avoid
No conditions to avoid anticipated.

Incompatible materials
acids, bases, amines

Hazardous decomposition products

Decomposition products:
Hazardous decomposition products:
carbon monoxide, carbon dioxide

Thermal decomposition:
No decomposition if correctly stored and handled.

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity
Assessment of acute toxicity: Of moderate toxicity after single ingestion. Of moderate toxicity after short-term inhalation. Of low toxicity after short-term skin contact.

Oral
Type of value: ATE
Value: 301 mg/kg

Tested as a preparation.

Information on: glutaral
Type of value: LD50
Species: rat (female)
Value: approx. 77 mg/kg (similar to OECD guideline 401)

Information on: Methanol
Type of value: LD50
Species: rat
Value: > 1187 - 2769 mg/kg (BASF-Test)

Inhalation
Type of value: ATE
Value: 1.09 mg/l
Determined for mist

Dermal
Type of value: ATE
Value: 3,790 mg/kg

Assessment other acute effects
Assessment of STOT single:

Causes temporary irritation of the respiratory tract.

Irritation / corrosion
Assessment of irritating effects: Corrosive! Damages skin and eyes.

Skin

Information on: glutaral
Species: rabbit
Result: Corrosive.
Method: similar to OECD guideline 404

Eye

Information on: glutaral
Species: rabbit
Result: Risk of serious damage to eyes.
Method: Draize test

Sensitization
Assessment of sensitization: The substance may cause sensitization of the respiratory tract.
Sensitization after skin contact possible.

Information on: glutaral
Open epicutaneous test (OET)
Species: guinea pig
Result: sensitizing

Species: human
Result: sensitizing

Aspiration Hazard
No aspiration hazard expected.

Chronic Toxicity/Effects

Repeated dose toxicity

Information on: glutaral
Assessment of repeated dose toxicity: After repeated exposure the prominent effect is local irritation. The substance may cause damage to the upper respiratory tract after repeated inhalation, as shown in animal studies.

Genetic toxicity

Information on: glutaral
Assessment of mutagenicity: The substance was mutagenic in various test systems with bacterias and cell cultures; however, these results could not be confirmed in tests with mammals.

Carcinogenicity

Assessment of carcinogenicity: None of the components in this product at concentrations greater than 0.1% are listed by IARC; NTP, OSHA or ACGIH as a carcinogen.

Reproductive toxicity

Information on: glutaral
Assessment of reproduction toxicity: The results of animal studies gave no indication of a fertility impairing effect.

Teratogenicity

Information on: glutaral
Assessment of teratogenicity: No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Other Information
The product has not been tested. The statement has been derived from the properties of the individual components.

Symptoms of Exposure

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Further symptoms and / or effects are not known so far

Medical conditions aggravated by overexposure
Contact may aggravate pulmonary disorders.

12. Ecological Information

Toxicity

Aquatic toxicity
Assessment of aquatic toxicity:
Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
The ecological data given are those of the active ingredient.

Toxicity to fish
LC50 (96 h) 0.8 mg/l, Salmo gairdneri, syn. O. mykiss (Fish test acute, static)
The details of the toxic effect relate to the nominal concentration.

LC50 (96 h) 6.2 mg/l, Cyprinodon variegatus (Fish test acute, static)
The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates
EC50 (48 h) 2.1 mg/l, Daphnia magna (Daphnia test acute, static)
The details of the toxic effect relate to the nominal concentration.

EC50 (96 h) 0.78 mg/l, Crassostrea virginica (OPP 72-3 (EPA-Guideline), Flow through.)
The statement of the toxic effect relates to the analytically determined concentration.

Aquatic plants
EC50 (72 h) 0.6 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static)
The statement of the toxic effect relates to the analytically determined concentration.

No observed effect concentration (72 h) 0.025 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static)
The statement of the toxic effect relates to the analytically determined concentration.

EC50 (72 h) 0.92 mg/l (growth rate), Skeletonema costatum (ISO/DIS 10253, static)
The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to fish
No observed effect concentration (97 d) 1.6 mg/l, Oncorhynchus mykiss (Flow through.)
The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to aquatic invertebrates
No observed effect concentration (21 d) 5.0 mg/l, Daphnia magna (OECD Guideline 211, semistatic)

Assessment of terrestrial toxicity
Toxic effects have been observed in studies with terrestric plants. Toxic effects have been observed in studies with soil living organisms.

Soil living organisms

Toxicity to soil dwelling organisms:
LC50 (14 d) 170 mg/kg, Eisenia foetida (OECD Guideline 207, artificial soil)
The details of the toxic effect relate to the nominal concentration.

EC10 (28 d) 10.45 mg/kg, soil dwelling microorganisms (OECD 217, natural soil)
The details of the toxic effect relate to the nominal concentration.

Toxicity to terrestrial plants

EC20 (19 d) 441 mg/kg, Vicia sativa (OECD Guideline 208)

Other terrestrial non-mammals
LD50 (14 d) 206 mg/kg, Anas platyrhynchos (other)

Microorganisms/Effect on activated sludge

Toxicity to microorganisms
OECD Guideline 209 aerobic
activated sludge, domestic/EC20 (30 min): approx. 15 mg/l
The details of the toxic effect relate to the nominal concentration.

Persistence and degradability

Assessment biodegradation and elimination (H2O)
Readily biodegradable (according to OECD criteria).

Elimination information

90 - 100 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Assessment biodegradation and elimination (H2O)

Information on: glutaral

Readily biodegradable (according to OECD criteria).

Elimination information

Information on: glutaral
90 - 100 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Assessment of stability in water
In contact with water the substance will hydrolyse slowly.

Information on Stability in Water (Hydrolysis)
$t_{1/2}$ > 1 a (50 °C), (Directive 92/69/EEC, C.7, pH 7)
In contact with water the substance will hydrolyse slowly.

Assessment of stability in water

Information on: glutaral

In contact with water the substance will hydrolyse slowly.

Bioaccumulative potential

Assessment bioaccumulation potential
No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Bioaccumulation potential
Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is not to be expected.

Assessment bioaccumulation potential

Information on: glutaral

No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Mobility in soil

Assessment transport between environmental compartments
The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is possible.

Information on: glutaral

The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is possible.

Additional information

Other ecotoxicological advice:
Data refer to a diluted aqueous solution of the substance.

13. Disposal considerations

Waste disposal of substance:

Dispose of in accordance with national, state and local regulations. It is the waste generator's responsibility to determine if a particular waste is hazardous under RCRA.

Container disposal:
Dispose of in a licensed facility. Recommend crushing, puncturing or other means to prevent unauthorized use of used containers.

RCRA:
This product meets the D002 (characteristic corrosivity) criteria.

14. Transport Information

Land transport
USDOT

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8, EHSM
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

Sea transport
IMDG

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8, EHSM
Marine pollutant:	YES
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

Air transport
IATA/ICAO

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

15. Regulatory Information

Federal Regulations

Registration status:

Biocide	TSCA, US	released / exempt

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

State regulations

State RTK	CAS Number	Chemical name
NJ	111-30-8	glutaral
PA	111-30-8	glutaral

Safe Drinking Water & Toxic Enforcement Act, CA Prop. 65:

WARNING: This product can expose you to chemicals including METHANOL, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

NFPA Hazard codes:
Health: 3 Fire: 1 Reactivity: 0 Special:

HMIS III rating
Health: 3 Flammability: 1 Physical hazard: 0

Labeling requirements under FIFRA

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label.

DANGER:
CORROSIVE.
CAUSES IRREVERSIBLE EYE DAMAGE.
CAUSES SKIN IRRITATION.
HARMFUL IF INHALED.
HARMFUL IF SWALLOWED.
HARMFUL IF ABSORBED THROUGH SKIN.
MAY CAUSE ALLERGIC SKIN REACTION.
CAUSES ASTHMATIC SIGNS AND SYMPTOMS IN HYPER-REACTIVE INDIVIDUALS.
Do not get in eyes, on skin, or on clothing.
Avoid inhalation of vapour.
Not to be used as an aerosol.
Do not swallow.
Wear protective eyeware (goggles or face shield).
Wear chemical resistant protective gloves.
Wear protective clothing.
Wash with plenty of water and soap thoroughly after handling.
Remove contaminated clothing immediately and clean before re-use or dispose it if necessary.

16. Other Information

SDS Prepared by:
BASF NA Product Regulations
SDS Prepared on: 2018/08/31

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our

operations on society and the environment during production, storage, transport, use and disposal of our products.

Myacide® GA 25 is a registered trademark of BASF Corporation or BASF SE
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END OF DATA SHEET

SDS no. S100
Version 8
Revision date 05-Oct-2020
Supersedes Date: 08-Sep-2017

Safety Data Sheet
Sand S100

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Sand S100
Product code S100

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Specific target organ toxicity - Repeated exposure	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to industrial incineration plant

_

Contains
Quartz, Crystalline silica

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Quartz, Crystalline silica	238-878-4	14808-60-7	60-100

3.2 Mixtures

Not applicable

Comments
This product contains a small quantity of quartz, crystalline silica. Prolonged and repeated exposure to concentrations of crystalline silica exceeding the workplace exposure limit (WEL) may lead to chronic lung disease such as silicosis.

4. First Aid Measures

4.1 First aid measures

Inhalation — If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion — Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact — Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention if irritation occurs.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
React with hydrofluoric acid (HF) forming toxic gas (SiF4).

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Vacuum up. Avoid generating dust. Put into suitable containers for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. For personal protection see section 8.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Provide appropriate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits.

Storage precautions Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, React with hydrofluoric acid (HF) forming toxic gas (SiF4) Strong oxidizing agents

Storage class Chemical storage.

Packaging materials Use specially constructed containers only. Bag with moisture barrier Paper bag (minimum 3 ply), or other industrial container designed for powders and granulated materials

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Quartz, Crystalline silica	0.1 mg/m³ TWA	0.1mg/m³TWArespirable dust	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Quartz, Crystalline silica	Not determined	0.1 mg/m³ TWA	0.03 mg/m³ OEL
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Quartz, Crystalline silica	1 mg/m³ MAC	0.1 mg/m³ TWA	0.1 mg/m³ TWA Confirmed carcinogen
Chemical Name	**Malaysia**	**Philippines**	**Russia**

Quartz, Crystalline silica	0.1 mg/m³ TWA	Not determined	3 mg/m³ STEL 1 mg/m³ TWA Fibrogenic substance 1177, 1178
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Quartz, Crystalline silica	0.025 mg/m³ TWA	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against dusts Safety glasses with side-shields Tightly fitting safety goggles

Hand protection Wear gloves according to EN 374 to protect against skin effects from powders Repeated or prolonged contact Use protective gloves made of: Nitrile Neoprene gloves Frequent change is advisable

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before eating, drinking or smoking Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state Solid
Appearance Granules
Odor Odorless
Color Tan
Odor threshold Not applicable

Property	Values	Remarks
pH	Not applicable	
pH @ dilution	No information available	
Melting / freezing point	> 1700 °C / 3092 °F	
Boiling point/range	No information available	

Flash point	Not applicable	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	Not applicable	
Specific gravity	2.6	@20 °C
Bulk density	1100 - 1600 kg/m³	
Relative density	No information available	
Water solubility	Insoluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

React with hydrofluoric acid (HF) forming toxic gas (SiF4).

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation.

10.5 Incompatible materials

Hydrofluoric acid (HF). Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough. May cause respiratory irritation. Repeated or prolonged inhalation of crystalline silica dust can cause delayed lung injury, and other diseases, including silicosis and lung cancer.

Eye contact Dust may cause mechanical irritation.

Skin contact Repeated exposure may cause skin dryness or cracking.

Ingestion Ingestion may cause stomach discomfort.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Quartz, Crystalline silica	No data available	No data available	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity Contains a known or suspected carcinogen. Crystalline silica dust is listed by IARC in Group 1 as known to cause lung cancer in humans, if inhaled.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of Exposure Inhalation. Skin contact. Eye contact.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Category 2.

Target organ effects Respiratory system. Lungs.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Quartz, Crystalline silica	No information available	No information available	No information available

12.2 Persistence and degradability

See component information below.

Chemical Name	Persistence and degradability
Quartz, Crystalline silica	Inorganic compound

12.3 Bioaccumulative potential

See component information below.

Chemical Name	Bioaccumulation
Quartz, Crystalline silica	Product/Substance is inorganic

12.4 Mobility

Mobility
The product is insoluble and sinks in water. See component information below.

Chemical Name	Mobility
Quartz, Crystalline silica	Insoluble in water

Mobility in soil
See component information below.

Chemical Name	Mobility in soil
Quartz, Crystalline silica	Not expected to adsorb on soil

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons
No poisons schedule number allocated

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by

Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Poh Yue Cheong
Supersedes Date:	08-Sep-2017
Revision date	05-Oct-2020
Version	8
This SDS has been revised in the following section(s)	All sections No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	3*
Flammability	0
Physical hazard	0
PPE	E

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SDS no. S521-2040-NRT
Version 1
Revision date 26-Apr-2016
Supersedes date None

Safety Data Sheet
CARBOPROP® NRT S521-2040-NRT

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name CARBOPROP® NRT S521-2040-NRT
Product code S521-2040-NRT

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a proppant in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to (EC) No. 1272/2008

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary Statements - EU (§28, 1272/2008)

This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

-

Contains

2.3 Other data

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not Applicable

4. First aid measures

4.1 First-Aid Measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which shall not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products
None known.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Avoid generating or breathing dust. Take up mechanically and collect in suitable container for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging material	Use specially constructed containers only.

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may

be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure
Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed.

Personal protective equipment

Eye protection	Safety glasses with side-shields. Tightly fitting safety goggles.
Hand protection	Use protective gloves made of:, Neoprene, Nitrile, PVC, Frequent change is advisable.
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment, Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181), At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.

Hygiene measures Wash hands before breaks and immediately after handling the product, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Granules
Odor	Odorless
Color	Brown Dark green Black
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution		
Melting/freezing point	> 2000 °C / 3632 °F	
Boiling point/range	Not Applicable	
Flash point		
Evaporation rate (BuAc =1)	Not Applicable	
Flammability (solid, gas)	Not Applicable	
Flammability Limits in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	3.15 - 3.65 g/cm3	
Bulk density	1.73 - 2.15 g/cm3	
Relative density	No information available	
Water solubility	Insoluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
Log Pow	No information available	

Explosive properties	Not Applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

10. Stability and reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust in high concentration may cause irritation of respiratory system.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not Applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.

Carcinogenicity	This product does not contain any known or suspected carcinogens.
Reproductive toxicity	No information available.
Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	No route of entry noted.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified.
Aspiration hazard	Not Applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4 Mobility in soil

Mobility
Insoluble in water.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.
EWC Waste disposal No.	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used. The following Waste Codes are only suggestions: 16 03 04 - inorganic wastes other than those mentioned in 16 03 03

14. Transport information

14.1 UN Number
Not regulated

14.2 Proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG Hazard class	Not regulated
ICAO Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG Packing group	Not regulated
ICAO Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not Applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code.

International inventories

USA (TSCA)	Complies
European Union (EINECS and ELINCS)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel
Revision date	26-Apr-2016
Version	1
The following sections have been revised:	New issue.

Full text of H-Statements referred to under sections 2 and 3

This product is not classified as hazardous therefore no (H) hazard statements assigned.

Disclaimer

The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. S521-2040
Version 6
Revision date 09-Jul-2018
Supersedes Date: 26-Apr-2016

Safety Data Sheet
CARBOPROP

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name CARBOPROP
Product code S521-2040

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a proppant in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Inhalation of dust in high concentration may cause irritation of respiratory system

Australian statement of hazardous/dangerous nature

Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation — If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion — Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact — Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye Contact — Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice — The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation — Please see Section 11. Toxicological Information for further information.

Ingestion — Please see Section 11. Toxicological Information for further information.

Skin contact — Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Fire or high temperatures create: Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Avoid generating or breathing dust. Take up mechanically and collect in suitable container for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits	NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Safety glasses with side-shields Tightly fitting safety goggles
Hand protection	Wear gloves according to EN 374 to protect against skin effects from powders Use protective gloves made of: Neoprene Nitrile PVC Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Granules
Odor	Odorless
Color	Brown Dark green Black
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	No information available	
Melting / freezing point	> 2000 °C / 3632 °F	
Boiling point/range	Not applicable	
Flash point	Not applicable	
Evaporation rate (BuAc =1)	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	Not applicable	
Vapor density	Not applicable	
Specific gravity	3.15 - 3.65 g/cm3	
Bulk density	1.73 - 2.15 g/cm3	
Relative density	No information available	
Water solubility	Insoluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust in high concentration may cause irritation of respiratory system.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.

Reproductive toxicity	No information available.
Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	No route of entry noted.

Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	Not applicable.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4 Mobility

Mobility
Insoluble in water.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	26-Apr-2016
Revision date	09-Jul-2018
Version	6
This SDS has been revised in the following section(s)	The following sections have been revised: 1, 7, 8, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

Disclaimer
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Appendix D.3 January 2022 Safety Data Sheets

SDS no. B499
Version 1
Revision date 10-Jun-2016
Supersedes date None

Safety Data Sheet
Natural Corrosion Inhibitor B499

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Natural Corrosion Inhibitor B499
Product code B499

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to (EC) No. 1272/2008

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary Statements - EU (§28, 1272/2008)

This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

-

Contains

2.3 Other data

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not Applicable

4. First aid measures

4.1 First-Aid Measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which shall not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Dust may form explosive mixture in air.

Hazardous combustion products
Fire or high temperatures create:, Carbon oxides (COx), Nitrogen oxides (NOx), Hydrogen cyanide (hydrocyanic acid), Thermal decomposition can lead to release of toxic and corrosive gases/vapors.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Sweep up and shovel into suitable containers for disposal. Use non-sparking tools and equipment. Avoid dust formation. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Keep away from open flames, hot surfaces and sources of ignition.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid heat, flames and other sources of ignition.
Storage class	Chemical storage.
Packaging material	Use specially constructed containers only.

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits	NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure
Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed.

Personal protective equipment

Eye protection	Safety glasses with side-shields. Tightly fitting safety goggles.
Hand protection	Repeated or prolonged contact:, Use protective gloves made of:, Butyl, Nitrile, Frequent change is advisable.
Respiratory protection	No personal respiratory protective equipment normally required, In case of insufficient ventilation wear suitable respiratory equipment, Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181), At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.

Hygiene measures Wash hands before eating, drinking or smoking, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Flakes Powder
Odor	Odorless
Color	Off-white
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	No information available	
pH @ dilution		
Melting/freezing point	260-280 °C / 500-536 °F	
Boiling point/range	No information available	
Flash point	No information available	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not Applicable	
Flammability Limits in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.5 - 0.7	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Miscible with water.	
Solubility in other solvents	No information available	
Autoignition temperature	500 °C / 932 °F	
Decomposition temperature	400 C	

Kinematic viscosity	No information available
Dynamic viscosity	No information available
Log Pow	No information available

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Dust may form explosive mixture in air.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation. Avoid heat, flames and other sources of ignition.

10.5 Incompatible materials

No materials to be especially mentioned.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust in high concentration may cause irritation of respiratory system.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not Applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.
Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Skin contact. Inhalation. Eye contact.
Routes of entry	No route of entry noted.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Not classified.
Aspiration hazard	Not Applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
No product level data available.

Toxicity to fish
No product level data available.

Toxicity to daphnia and other aquatic invertebrates
No product level data available.

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility in soil

Mobility
The product is miscible with water. May spread in water systems.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.
EWC Waste disposal No.	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used. The following Waste Codes are only suggestions: EWC waste disposal No: Waste Code: 16 03 06 - organic wastes other than those mentioned in 16 03 05 01 04 10 – dusty and powdery wastes other than those mentioned in 01 04 07,

14. Transport information

14.1 UN Number
Not regulated

14.2 Proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG Hazard class	Not regulated
ICAO Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG Packing group	Not regulated
ICAO Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions

Not Applicable

Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Australian Standard for the Uniform Scheduling of Drugs and Poisons
No Poisons Schedule number allocated

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG Code) for transport by road or rail.

International inventories

USA (TSCA)	Complies
European Union (EINECS and ELINCS)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel

Revision date	10-Jun-2016
Version	1
The following sections have been revised:	New issue.

Full text of H-Statements referred to under sections 2 and 3

This product is not classified as hazardous therefore no (H) hazard statements assigned.

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. B645-4070
Version 1
Revision date 28-Feb-2019
Supersedes Date: None

Safety Data Sheet
40/70-Mesh Sand B645

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name 40/70-Mesh Sand B645
Product code B645-4070
Country Limitations Limited to use in these countries: Australia

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a proppant in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Specific target organ toxicity - Repeated exposure	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Quartz, Crystalline Silica

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Quartz, Crystalline Silica	238-878-4	14808-60-7	60 - 100

3.2 Mixtures

Not applicable

Comments
IARC Monographs, Vol. 68, 1997, concludes that there is sufficient evidence that inhaled crystalline silica in the form of quartz or cristobalite from occupational sources causes cancer in humans. IARC Classification Group I.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Seek medical attention if irritation occurs.

Skin contact Wash off immediately with soap and plenty of water. Remove contaminated clothing and shoes. Seek medical attention if irritation occurs.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing dust; if exposed to high dust concentration, leave area immediately. Do not get on skin or clothing. Wash thoroughly after handling. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading.

Methods for cleaning up
Avoid dust formation. Sweep up and shovel into suitable containers for disposal. Material becomes slippery when wet. Use caution if wet.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid handling causing generation of dust. Material becomes slippery when wet. Use caution if wet. Avoid breathing dust; if exposed to high dust concentration, leave area immediately.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Do not eat, drink or smoke when using this product Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits.

Storage precautions Follow safe warehousing practices regarding palletizing, banding, shrink-wrapping and/or stacking. Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, Oxidizing agents Hydrofluoric acid (HF)

Storage class Chemical storage.

Packaging materials Paper bag (minimum 3 ply), or other industrial container designed for powders and granulated materials

8. Exposure Controls/Personal Protection

8.1 Control parameters

Component Information

Chemical Name	Arabic	Australia	Egypt
Quartz, Crystalline Silica	0.1 mg/m³ TWA	0.1mg/m³TWArespirable dust	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Quartz, Crystalline Silica	Not determined	0.1 mg/m³ TWA	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Quartz, Crystalline Silica	1 mg/m³ MAC	Not determined	0.1 mg/m³ TWA Confirmed carcinogen
Chemical Name	**Malaysia**	**Philippines**	**Russia**

Quartz, Crystalline Silica	0.1 mg/m³ TWA	Not determined	3 mg/m³ STEL 1 mg/m³ TWA Fibrogenic substance glass;regulated under Quartz 1123, 1124
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Quartz, Crystalline Silica	0.025 mg/m³ TWA	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required. Keep airborne concentrations below exposure limits

Personal protective equipment

Eye protection	Safety glasses with side-shields Tightly fitting safety goggles
Hand protection	Wear chemical resistant gloves such as nitrile or neoprene. Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Granules
Odor	Odorless
Color	Tan or White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	No information available	
Melting / freezing point	> 1700 °C / 3092 °F	
Boiling point/range	No information available	
Flash point	Not applicable	

Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	2.55 - 2.75	@20 °C
Bulk density	1450 -1650 kg/m^3	
Relative density	No information available	
Water solubility	Insoluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity		
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

React with hydrofluoric acid (HF) forming toxic gas (SiF4).

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation.

10.5 Incompatible materials

Hydrofluoric acid (HF). Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough. Repeated or prolonged inhalation of crystalline silica dust can cause delayed lung injury, and other diseases, including silicosis and lung cancer.

Eye contact Dust may cause mechanical irritation.

Skin contact Repeated exposure may cause skin dryness or cracking.

Ingestion Ingestion may cause stomach discomfort.

Unknown acute toxicity Not applicable.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Quartz, Crystalline Silica	= 500 mg/kg (Rat)	No data available	No data available

Sensitization Not classified.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity Contains a known or suspected carcinogen. Crystalline silica dust is listed by IARC in Group 1 as known to cause lung cancer in humans, if inhaled.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of Exposure Inhalation. Skin contact. Eye contact.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Category 2.

Target organ effects Lungs. Respiratory system.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Quartz, Crystalline Silica	No information available	No information available	No information available

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

Chemical Name	Persistence and degradability
Quartz, Crystalline Silica	Inorganic compound

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

Chemical Name	Bioaccumulation
Quartz, Crystalline Silica	Product/Substance is inorganic No bioaccumulation potential

12.4 Mobility

Mobility
Insoluble in water.

Chemical Name	Mobility
Quartz, Crystalline Silica	No information available

Mobility in soil
No information available.

Chemical Name	Mobility in soil
Quartz, Crystalline Silica	No information available

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known. Check for additional information in sect. 7.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons
No poisons schedule number allocated

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals)
Revision date	28-Feb-2019
Version	1
This SDS has been revised in the following section(s)	New issue.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	1*
Flammability	0
Physical hazard	0
PPE	E

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SDS no. F112
Version 3
Revision date 15-Aug-2018
Supersedes Date: 07-May-2018

Safety Data Sheet
Surfactant F112

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Surfactant F112
Product code F112

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Surfactant in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2

Environmental hazards

Chronic aquatic toxicity	Category 3

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements
P273 - Avoid release to the environment
P280 - Wear protective gloves and eye/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P391 - Collect spillage
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Supplementary precautionary statements
P337 + P313 - If eye irritation persists: Get medical advice/attention
P264 - Wash face, hands and any exposed skin thoroughly after handling
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse

Contains
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-

Dicoco dimethyl quaternary ammonium chloride

Propan-2-ol

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Inhalation of vapors in high concentration may cause irritation of respiratory system

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	500-077-5	31726-34-8	10-<20
Dicoco dimethyl quaternary ammonium chloride	263-087-6	61789-77-3	0.5-<1.0
Propan-2-ol	200-661-7	67-63-0	0.1-<0.25

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion If swallowed, call a poison control center or doctor immediately. Do NOT induce vomiting. If conscious, drink plenty of water.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Get medical attention if irritation persists.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Extinguish with carbon dioxide, dry chemical, foam or waterspray.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors Carbon oxides (COx), Nitrogen oxides (NOx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 3Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear suitable protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13). After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Do not get in eyes, on skin or on clothing. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands before eating, drinking or smoking Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Avoid contact with: Strong oxidizing agents
Storage class	Chemical storage.

Packaging materials Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Component Information

Chemical Name	Arabic	Australia	Egypt
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA	500ppmSTEL 1230mg/m³STEL 400ppmTWA 983mg/m³TWA	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA
Chemical Name	**India**	**Indonesian**	**Japan**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	Not determined	400 ppm TWA 983 mg/m³ TWA 500 ppm STEL 1230 mg/m³ STEL	200 ppm ACL
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	10 mg/m³ MAC	1225 mg/m³ STEL 500 ppm STEL	500 ppm STEL 1230 mg/m³ STEL 400 ppm TWA 983 mg/m³ TWA
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	400 ppm TWA 983 mg/m³ TWA	400 ppm TWA 980 mg/m³ TWA	50 mg/m³ STEL 10 mg/m³ TWA
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not determined	Not determined	Not determined
Dicoco dimethyl quaternary ammonium chloride	Not determined	Not determined	Not determined
Propan-2-ol	400 ppm TWA	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment
Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly

	fitting safety goggles
Hand protection	Impervious gloves made of: Nitrile or Butyl Break through time >480 minutes Glove thickness 0.5 mm Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	No personal respiratory protective equipment normally required In case of insufficient ventilation wear suitable respiratory equipment Use respirator with organic vapor/acid gas protection (E, yellow) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odor	Alcohol
Color	Clear Yellow
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	9-11	
pH @ dilution	No information available	Not applicable
Melting / freezing point	5 °C / 41 °F	
Boiling point/range	~ 100 °C / 212 °F	
Flash point	> 93.3 °C / > 199.4 °F	PMCC
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.99 - 1.03 g/cm^3	@ 20 °C
Bulk density	No information available	
Relative density	~ 1.0	@ 20°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	5-50 mPa s	@ 16 °C
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	< 1
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of vapors in high concentration may cause irritation of respiratory system.
Eye contact	Causes serious eye irritation.
Skin contact	Causes skin irritation.
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.
Unknown acute toxicity	Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation

Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	LD50: 1250 mg/kg, rat, (based on data from similar substance)	LD50: > 2000 mg/kg, rat, (based on data from similar component)	No data available
Dicoco dimethyl quaternary ammonium chloride	= 960 mg/kg (Rat)	LD50 > 2930 mg/kg, rabbit	No data available
Propan-2-ol	= 1870 mg/kg (Rat)	= 4059 mg/kg (Rabbit)	= 72600 mg/m³ (Rat) 4 h

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Eye contact. Skin contact. Inhalation.

Routes of entry Eye contact. Skin contact.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

Harmful to aquatic life with long lasting effects

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	LC50 96h, Brachydanio rerio (zebrafish): > 100 mg/l (test based on similar component)	EC50, 72h: > 100 mg/kg (based on similar substance)	EC50, 48h, Daphnia magna (Water flea): > 100 mg/l (based on similar product)
Dicoco dimethyl quaternary ammonium chloride	No information available	No information available	EC50, 48h, Daphnia : 0.01 mg/l
Propan-2-ol	> 1400000 µg/L LC50 Lepomis macrochirus 96 h = 11130 mg/L LC50 Pimephales promelas 96 h = 9640 mg/L LC50 Pimephales promelas 96 h	> 1000 mg/L EC50 Desmodesmus subspicatus 96 h > 1000 mg/L EC50 Desmodesmus subspicatus 72 h	= 13299 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

Product is biodegradable.

Chemical Name	Persistence and degradability
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Readily biodegradable
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	Readily biodegradable

12.3 Bioaccumulative potential

Does not bioaccumulate.

Chemical Name	Bioaccumulation
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Not likely to bioaccumulate
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	No bioaccumulation potential

12.4 Mobility

Mobility
Soluble in water.

Chemical Name	Mobility
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	Miscible in water
Dicoco dimethyl quaternary ammonium chloride	Soluble in water
Propan-2-ol	Soluble in water

Mobility in soil
No information available.

Chemical Name	Mobility in soil
Poly(oxy-1,2-ethanediyl), alphahexyl-omega-hydroxy-	No information available
Dicoco dimethyl quaternary ammonium chloride	No information available
Propan-2-ol	No information available

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable
Hazchem code ADG 3Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Does not comply
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	07-May-2018
Revision date	15-Aug-2018
Version	3
This SDS has been revised in the following section(s)	2, 12, 14, 16 There have been changes with regard to classification.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2
Flammability	1
Physical hazard	0
PPE	X

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CONSOLIDATED CHEMICAL CO.
ABN: 34 527 060 773 ACN: 005 056 502

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glutaraldehyde 25% solution
CONSOLIDATED CHEMICAL CO

Chemwatch Hazard Alert Code: **3**

Chemwatch: **45628**
Version No: **5.1.3.1**
Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: **01/11/2019**
Print Date: **05/05/2021**
S.GHS.AUS.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	glutaraldehyde 25% solution
Proper shipping name	CORROSIVE LIQUID, TOXIC, N.O.S. (contains glutaraldehyde)
Chemical formula	Not Applicable
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Biocide for sterilization of endoscopic instruments, polyester, rubber or plastic equipment which is not suitable for heat sterilized. As a biocide in water treatment, biocide in aircraft, portable toilets. In disinfectant solutions for animal housing. Preservative in mineral oils. [~Medicine ~]

Details of the supplier of the safety data sheet

Registered company name	**CONSOLIDATED CHEMICAL CO**
Address	52-62 Waterview Close, Dandenong South VIC 3175 Australia
Telephone	03 8903 3444
Fax	03 9799 7666
Website	www.conchem.com.au
Email	melb@conchem.com.au

Emergency telephone number

Association / Organisation	**CONSOLIDATED CHEMICAL CO**	**CHEMWATCH EMERGENCY RESPONSE**
Emergency telephone numbers	**1800 839 984**	**+61 2 9186 1132**
Other emergency telephone numbers	**Not Available**	**+61 1800 951 288**

Once connected and if the message is not in your prefered language then please dial 01

SECTION 2 Hazards identification

Classification of the substance or mixture

HAZARDOUS CHEMICAL. DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

Poisons Schedule	S6

Page 1 continued...

Classification [1]	Corrosive to Metals Category 1, Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4, Skin Corrosion/Irritation Category 1B, Serious Eye Damage/Eye Irritation Category 1, Skin Sensitizer Category 1, Respiratory Sensitizer Category 1, Acute Aquatic Hazard Category 1
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI*

Label elements

Hazard pictogram(s)	
Signal word	**Danger**

Hazard statement(s)

H290	May be corrosive to metals.
H302	Harmful if swallowed.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H400	Very toxic to aquatic life.

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

P260	Do not breathe mist/vapours/spray.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
P284	[In case of inadequate ventilation] wear respiratory protection.
P234	Keep only in original packaging.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P272	Contaminated work clothing should not be allowed out of the workplace.

Precautionary statement(s) Response

P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor/physician/first aider.
P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/physician/first aider.
P302+P352	IF ON SKIN: Wash with plenty of water.
P363	Wash contaminated clothing before reuse.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P390	Absorb spillage to prevent material damage.
P391	Collect spillage.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/physician/first aider if you feel unwell.

Precautionary statement(s) Storage

P405	Store locked up.

Continued...

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
111-30-8	25	glutaraldehyde
7732-18-5	75	water

Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available*

SECTION 4 First aid measures

Description of first aid measures

Eye Contact	If this product comes in contact with the eyes: ▸ Immediately hold eyelids apart and flush the eye continuously with running water. ▸ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▸ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes. ▸ Transport to hospital or doctor without delay. ▸ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: ▸ Immediately flush body and clothes with large amounts of water, using safety shower if available. ▸ Quickly remove all contaminated clothing, including footwear. ▸ Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre. ▸ Transport to hospital, or doctor.
Inhalation	▸ If fumes or combustion products are inhaled remove from contaminated area. ▸ Lay patient down. Keep warm and rested. ▸ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▸ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▸ Transport to hospital, or doctor, without delay.
Ingestion	▸ For advice, contact a Poisons Information Centre or a doctor at once. ▸ Urgent hospital treatment is likely to be needed. ▸ If swallowed do **NOT** induce vomiting. ▸ If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. ▸ Observe the patient carefully. ▸ Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. ▸ Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. ▸ Transport to hospital or doctor without delay. ▸ Avoid giving milk or oils. ▸ Avoid giving alcohol. ▸ If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus.

Indication of any immediate medical attention and special treatment needed

Any material aspirated during vomiting may produce lung injury. Therefore emesis should not be induced mechanically or pharmacologically. Mechanical means should be used if it is considered necessary to evacuate the stomach contents; these include gastric lavage after endotracheal intubation. If spontaneous vomiting has occurred after ingestion, the patient should be monitored for difficult breathing, as adverse effects of aspiration into the lungs may be delayed up to 48 hours.
For simple aldehydes:

BASIC TREATMENT

▸ Establish a patent airway with suction where necessary.
▸ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
▸ Administer oxygen by non-rebreather mask at 10 to 15 l/min.

Continued...

- Monitor and treat, where necessary, for pulmonary oedema .
- Monitor and treat, where necessary, for shock.
- **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.
- Give activated charcoal.

ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Consider intubation at first sign of upper airway obstruction resulting from oedema.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

EMERGENCY DEPARTMENT

- Laboratory analysis of complete blood count, serum electrolytes, BUN, creatinine, glucose, urinalysis, baseline for serum aminotransferases (ALT and AST), calcium, phosphorus and magnesium, may assist in establishing a treatment regime. Other useful analyses include anion and osmolar gaps, arterial blood gases (ABGs), chest radiographs and electrocardiographs.
- Positive end-expiratory pressure (PEEP)-assisted ventilation may be required for acute parenchymal injury or adult respiratory distress syndrome.
- Treat bronchospasm in a similar manner to that employed for reactive airway disease. Severe exposures may require inhaled corticosteroids.
- Sodium bicarbonate may correct acidosis.
- Haemodialysis may assist in severely symptomatic patients.
- Consult a toxicologist as necessary.

BRONSTEIN, A.C. and CURRANCE, P.L.
EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 Firefighting measures

Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.
Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.
In such an event consider:

- foam.

Special hazards arising from the substrate or mixture

Fire Incompatibility	None known.

Advice for firefighters

Fire Fighting	- Alert Fire Brigade and tell them location and nature of hazard. - Wear full body protective clothing with breathing apparatus. - Prevent, by any means available, spillage from entering drains or water course. - Use fire fighting procedures suitable for surrounding area.
Fire/Explosion Hazard	- The material is not readily combustible under normal conditions. - However, it will break down under fire conditions and the organic component may burn. - Not considered to be a significant fire risk. - Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and produces toxic fumes of: carbon dioxide (CO2) aldehydes other pyrolysis products typical of burning organic material.
HAZCHEM	2X

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Continued...

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	‣ Clean up all spills immediately. ‣ Avoid breathing vapours and contact with skin and eyes. ‣ Control personal contact with the substance, by using protective equipment. ‣ Contain and absorb spill with sand, earth, inert material or vermiculite.
Major Spills	‣ **DO NOT** touch the spill material ‣ Clear area of personnel and move upwind. ‣ Alert Fire Brigade and tell them location and nature of hazard. ‣ Wear full body protective clothing with breathing apparatus. ‣ Prevent, by any means available, spillage from entering drains or water course.

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	‣ **DO NOT** allow clothing wet with material to stay in contact with skin ‣ Avoid all personal contact, including inhalation. ‣ Wear protective clothing when risk of exposure occurs. ‣ Use in a well-ventilated area. ‣ Avoid contact with moisture.
Other information	‣ Store in original containers. ‣ Keep containers securely sealed. ‣ Store in a cool, dry, well-ventilated area. ‣ Store away from incompatible materials and foodstuff containers.

Conditions for safe storage, including any incompatibilities

Suitable container	‣ Glass container is suitable for laboratory quantities ‣ Lined metal can, lined metal pail/ can. ‣ Plastic pail. ‣ Polyliner drum. ‣ Packing as recommended by manufacturer. For low viscosity materials ‣ Drums and jerricans must be of the non-removable head type. ‣ Where a can is to be used as an inner package, the can must have a screwed enclosure. For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.): ‣ Removable head packaging; ‣ Cans with friction closures and ‣ low pressure tubes and cartridges may be used.
Storage incompatibility	‣ Flammable and/or toxic gases are generated by the combination of aldehydes with azo, diazo compounds, dithiocarbamates, nitrides, and strong reducing agents. ‣ Many aldehydes are incompatible with strong acids, amines, strong oxidisers, and alkaline materials. ‣ Several medium range aldehydes ignite in air, particularly if exposure is increased by sorption on paper or cloth - ignition often occurs within 2 hours Glutaraldehyde: ‣ is a strong reducing agent ‣ reacts with water forming an aqueous polymer solution ‣ reacts violently with strong oxidisers, strong acids, bromine, ketones ‣ is incompatible with caustics, ammonia, amines, acetophenone, acetyl benzene, xylidenes ‣ the activated form (an alkaline solutions) react readily with alcohol, ketones, amines, hydrazines and proteins ‣ Incidents involving interaction of active oxidants and reducing agents, either by design or accident, are usually very energetic and examples of so-called redox reactions. ‣ Avoid strong bases.



+	x	+	x	+	+	+

X — *Must not be stored together*
0 — *May be stored together with specific preventions*
+ — *May be stored together*

Continued...

Note: Depending on other risk factors, compatibility assessment based on the table above may not be relevant to storage situations, particularly where large volumes of dangerous goods are stored and handled. Reference should be made to the Safety Data Sheets for each substance or article and risks assessed accordingly.

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

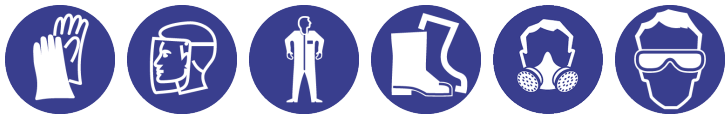
Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	glutaraldehyde	Glutaraldehyde	Not Available	Not Available	0.1 ppm / 0.41 mg/m3	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
glutaraldehyde	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
glutaraldehyde	Not Available	Not Available
water	Not Available	Not Available

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.
Personal protection	
Eye and face protection	‣ Chemical goggles. ‣ Full face shield may be required for supplementary but never for primary protection of eyes. ‣ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task.
Skin protection	See Hand protection below
Hands/feet protection	Latex rubber gloves are not recommended [NIOSH]. ‣ Wear chemical protective gloves, e.g. PVC. ‣ Wear safety footwear or safety gumboots, e.g. Rubber ‣ When handling corrosive liquids, wear trousers or overalls outside of boots, to avoid spills entering boots. **NOTE:** ‣ The material may produce skin sensitisation in predisposed individuals. Care must be taken, when removing gloves and other protective equipment, to avoid all possible skin contact. ‣ Contaminated leather items, such as shoes, belts and watch-bands should be removed and destroyed. The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care.
Body protection	See Other protection below
Other protection	‣ Overalls. ‣ PVC Apron. ‣ PVC protective suit may be required if exposure severe. ‣ Eyewash unit.

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:
"Forsberg Clothing Performance Index".

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Continued...

The effect(s) of the following substance(s) are taken into account in the ***computer-generated*** selection:
glutaraldehyde 25% solution

Material	CPI
BUTYL	A
NEOPRENE	A
VITON	A
NATURAL RUBBER	C
PVA	C
PVC	C

* CPI - Chemwatch Performance Index
A: Best Selection
B: Satisfactory; may degrade after 4 hours continuous immersion
C: Poor to Dangerous Choice for other than short term immersion
NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -
* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1	-
up to 50	1000	-	A-AUS / Class 1
up to 50	5000	Airline *	-
up to 100	5000	-	A-2
up to 100	10000	-	A-3
100+			Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand
A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Colourless liquid; soluble in water. Sharp irritating odour. Vapours may be irritating in concentrations of about 0.3 ppm in air. Soluble in alcohol and benzene.

Physical state	Liquid	**Relative density (Water= 1)**	1.13 @ 20 C
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	<7	**Decomposition temperature**	Not Available
Melting point / freezing point (°C)	-21 freezing pt	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	101.2	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Non Flammable	**Taste**	Not Available
Evaporation rate	Slow	**Explosive properties**	Not Available
Flammability	Non Flammable	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Applicable	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Applicable	**Volatile Component (%vol)**	50
Vapour pressure (kPa)	1.99	**Gas group**	Not Available
Solubility in water	Miscible	**pH as a solution (1%)**	<7
Vapour density (Air = 1)	3.5	**VOC g/L**	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	‣ Unstable in the presence of incompatible materials. ‣ Product is considered stable. ‣ Hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7

Continued...

Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may produce toxic effects. Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo. Inhalation hazard is increased at higher temperatures. Glutaraldehyde strongly irritates the eyes, nose, airways and skin. It causes chest tightness, excessive secretion of tears, wetness and crusting around the face and excessive salivation. There may be distinct acute nervous behaviour and liver damage. Chronic exposures may cause lung congestion, kidney and adrenal damage, sluggishness, weight loss and loss of appetite. Acute effects from inhalation of high vapour concentrations may be chest and nasal irritation with coughing, sneezing, headache and even nausea. Exposure to aldehydes causes neurological symptoms such as headache, drowsiness, dizziness, seizures, depression and coma. Cardiovascular involvement may result in increased heart rate, collapse and low blood pressure; respiratory effects include throat spasms, irritation, difficulty swallowing, pulmonary oedema and an asthma-like condition.
Ingestion	Accidental ingestion of the material may be harmful; animal experiments indicate that ingestion of less than 150 gram may be fatal or may produce serious damage to the health of the individual. The material can produce chemical burns within the oral cavity and gastrointestinal tract following ingestion. Swallowing of the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis; serious consequences may result. (ICSC13733) Animal testing showed that glutaraldehyde can cause kidney damage, congestion and distension of the stomach and intestines, congestion of the liver, spleen, kidney and adrenal glands, and bleeding and congestion of the lungs. Death has occurred at sufficiently high doses. Other toxic effects include sluggishness, excessive tear secretion, diarrhoea and crusting around the nose.
Skin Contact	Skin contact with the material may be harmful; systemic effects may result following absorption. The material can produce chemical burns following direct contact with the skin. Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. A test in Sweden revealed that hospital workers exposed to glutaraldehyde had higher rates of skin disorders, such as contact dermatitis, compared to those who were not exposed. In Australia, skin inflammation has been observed in different types of workers exposed to glutaraldehyde, including endoscopy nurses, hospital cleaners, radiographers and dental assistants. Facial irritation was reported in egg collectors spraying eggs with a glutaraldehyde sanitising solution. Animal testing showed that cumulative toxicity or death may occur with repeated skin contact with 25-50% glutaraldehyde, but not at a concentration of 5% or less.
Eye	The material can produce chemical burns to the eye following direct contact. Vapours or mists may be extremely irritating. If applied to the eyes, this material causes severe eye damage. The vapour when concentrated has pronounced eye irritation effects and this gives some warning of high vapour concentrations. If eye irritation occurs seek to reduce exposure with available control measures, or evacuate area. Exposure to glutaraldehyde has resulted in eye irritation in a number of cases, including endoscopy nurses and other hospital workers. Solutions splashed into the eye may cause irritation, pain and increased sensitivity to light. Animal testing showed that glutaraldehyde can irritate the conjunctiva and injure the cornea. Solutions greater than 0.1% in strength are potentially hazardous.
Chronic	Repeated or prolonged exposure to corrosives may result in the erosion of teeth, inflammatory and ulcerative changes in the mouth and necrosis (rarely) of the jaw. Bronchial irritation, with cough, and frequent attacks of bronchial pneumonia may ensue. Inhaling this product is more likely to cause a sensitisation reaction in some persons compared to the general population. Skin contact with the material is more likely to cause a sensitisation reaction in some persons compared to the general population. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Low concentrations cause skin reddening and irritation, occupational asthma, nasal discharge, sneezing and congestion. Long term exposure may cause chronic fatigue. There may be reduced body weight and damage to the nose with repeated high doses. It does not cause changes to foetal development, but may cause blood cancers (leukaemias).

glutaraldehyde 25% solution	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
glutaraldehyde	**TOXICITY**	**IRRITATION**
	Dermal (rabbit) LD50: >2000 mg/kg[1]	Eye (rabbit): 0.25mg/24h-SEVERE

Continued...

	Inhalation(Rat) LC50; 0.1 mg/l4h[2]	Eye (rabbit): 1 mg-SEVERE
	Oral(Rat) LD50; 154 mg/kg[1]	Skin (human): 6 mg/3d-int-SEVERE
		Skin (rabbit): 13 mg open-mild
		Skin (rabbit): 2 mg/24h-SEVERE
water	**TOXICITY**	**IRRITATION**
	Oral(Rat) LD50; >90000 mg/kg[2]	Not Available
Legend:	*1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances*	

glutaraldehyde 25% solution	The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may produce respiratory tract irritation, and result in damage to the lung including reduced lung function. The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
GLUTARALDEHYDE	The following information refers to contact allergens as a group and may not be specific to this product. Contact allergies quickly manifest themselves as contact eczema, more rarely as urticaria or Quincke's oedema. The pathogenesis of contact eczema involves a cell-mediated (T lymphocytes) immune reaction of the delayed type. Other allergic skin reactions, e.g. contact urticaria, involve antibody-mediated immune reactions. The significance of the contact allergen is not simply determined by its sensitisation potential: the distribution of the substance and the opportunities for contact with it are equally important. Allergic reactions involving the respiratory tract are usually due to interactions between IgE antibodies and allergens and occur rapidly. Allergic potential of the allergen and period of exposure often determine the severity of symptoms. Some people may be genetically more prone than others, and exposure to other irritants may aggravate symptoms. Allergy causing activity is due to interactions with proteins. Attention should be paid to atopic diathesis, characterised by increased susceptibility to nasal inflammation, asthma and eczema. Exogenous allergic alveolitis is induced essentially by allergen specific immune-complexes of the IgG type; cell-mediated reactions (T lymphocytes) may be involved. Such allergy is of the delayed type with onset up to four hours following exposure. The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.
WATER	No significant acute toxicological data identified in literature search.
glutaraldehyde 25% solution & GLUTARALDEHYDE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. Animal testing shows that glutaraldehyde has a high acute toxicity through inhalation and it may cause lung damage. It is corrosive to the skin and eyes and exposure to its vapours has caused irritation to the nose and breathing difficulties. It can sensitise skin and irritate the joints in animal testing. Prolonged skin contact can result in absorption through the skin (although absorption rates are low) according to laboratory testing with human skin tissue.

Acute Toxicity	✔	**Carcinogenicity**	✘
Skin Irritation/Corrosion	✔	**Reproductivity**	✘
Serious Eye Damage/Irritation	✔	**STOT - Single Exposure**	✘
Respiratory or Skin sensitisation	✔	**STOT - Repeated Exposure**	✘
Mutagenicity	✘	**Aspiration Hazard**	✘

Legend: ✘ *– Data either not available or does not fill the criteria for classification*
✔ *– Data available to make classification*

SECTION 12 Ecological information

Toxicity

	Endpoint	Test Duration (hr)	Species	Value	Source
glutaraldehyde 25% solution	Not Available	Not Available	Not Available	Not Available	Not Available

Continued...

glutaraldehyde	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	NOEC(ECx)	672h	Crustacea	10mg/l	1
	EC50	72h	Algae or other aquatic plants	0.375mg/l	2
	EC50	48h	Crustacea	0.002-0.004mg/L	4
	LC50	96h	Fish	0.022mg/L	4
	EC50	96h	Algae or other aquatic plants	<=0.004mg/L	4

water	**Endpoint**	**Test Duration (hr)**	**Species**	**Value**	**Source**
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend:	*Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data*

Very toxic to aquatic organisms.
Do NOT allow product to come in contact with surface waters or to intertidal areas below the mean high water mark. Do not contaminate water when cleaning equipment or disposing of equipment wash-waters.
Wastes resulting from use of the product must be disposed of on site or at approved waste sites.
Glutaraldehyde is a hydrophilic substance that will mainly partition to water, with minor amounts partitioning to the atmosphere following release to the environment. Hydrolysis is slow, but glutaraldehyde, like other aldehydes, undergoes aerial oxidation in solution. It biodegrades rapidly in aerobic and anaerobic aquatic environments at subcidal concentrations (below 10 mg/L) and will not bioaccumulate. Tropospheric degradation is also rapid.
Prevent, by any means available, spillage from entering drains or water courses.
DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
glutaraldehyde	LOW	LOW
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
glutaraldehyde	LOW (LogKOW = -0.1821)

Mobility in soil

Ingredient	Mobility
glutaraldehyde	HIGH (KOC = 1.094)

SECTION 13 Disposal considerations

Waste treatment methods

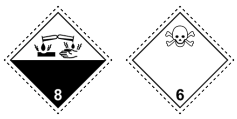
Product / Packaging disposal	▸ Containers may still present a chemical hazard/ danger when empty. ▸ Return to supplier for reuse/ recycling if possible. Otherwise: ▸ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. ▸ Where possible retain label warnings and SDS and observe all notices pertaining to the product. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: ▸ Reduction ▸ Reuse ▸ Recycling ▸ Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. ▸ **DO NOT** allow wash water from cleaning or process equipment to enter drains. ▸ It may be necessary to collect all wash water for treatment before disposal. ▸ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▸ Where in doubt contact the responsible authority.

Continued...

	▸ Recycle wherever possible. ▸ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▸ Treat and neutralise at an approved treatment plant. Treatment should involve: Neutralisation followed by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or Incineration in a licensed apparatus (after admixture with suitable combustible material) ▸ Decontaminate empty containers.

SECTION 14 Transport information

Labels Required

	
Marine Pollutant	
HAZCHEM	2X

Land transport (ADG)

UN number	2922
UN proper shipping name	CORROSIVE LIQUID, TOXIC, N.O.S. (contains glutaraldehyde)
Transport hazard class(es)	Class: 8 Subrisk: 6.1
Packing group	III
Environmental hazard	Environmentally hazardous
Special precautions for user	Special provisions: 223 274 Limited quantity: 5 L

Air transport (ICAO-IATA / DGR)

UN number	2922
UN proper shipping name	Corrosive liquid, toxic, n.o.s. * (contains glutaraldehyde)
Transport hazard class(es)	ICAO/IATA Class: 8 ICAO / IATA Subrisk: 6.1 ERG Code: 8P
Packing group	III
Environmental hazard	Environmentally hazardous
Special precautions for user	Special provisions: A3 A803 Cargo Only Packing Instructions: 856 Cargo Only Maximum Qty / Pack: 60 L Passenger and Cargo Packing Instructions: 852 Passenger and Cargo Maximum Qty / Pack: 5 L Passenger and Cargo Limited Quantity Packing Instructions: Y841 Passenger and Cargo Limited Maximum Qty / Pack: 1 L

Sea transport (IMDG-Code / GGVSee)

UN number	2922
UN proper shipping name	CORROSIVE LIQUID, TOXIC, N.O.S. (contains glutaraldehyde)

Continued...

Transport hazard class(es)	IMDG Class	8
	IMDG Subrisk	6.1
Packing group	III	
Environmental hazard	Marine Pollutant	
Special precautions for user	EMS Number	F-A , S-B
	Special provisions	223 274
	Limited Quantities	5 L

Transport in bulk according to Annex II of MARPOL and the IBC code

Product name	Pollution Category	Ship Type
Glutaraldehyde solutions (50% or less)	Y	3

Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
glutaraldehyde	Not Available
water	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
glutaraldehyde	Not Available
water	Not Available

SECTION 15 Regulatory information

Safety, health and environmental regulations / legislation specific for the substance or mixture

glutaraldehyde is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 2
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6
Australian Inventory of Industrial Chemicals (AIIC)

water is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	Yes
Canada - NDSL	No (glutaraldehyde; water)
China - IECSC	Yes
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	Yes
Korea - KECI	Yes
New Zealand - NZIoC	Yes
Philippines - PICCS	Yes
USA - TSCA	Yes
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	Yes

Continued...

National Inventory	Status
Russia - FBEPH	Yes
Legend:	*Yes = All CAS declared ingredients are on the inventory* *No = One or more of the CAS listed ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)*

SECTION 16 Other information

Revision Date	01/11/2019
Initial Date	01/11/2009

SDS Version Summary

Version	Date of Update	Sections Updated
5.1.1.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS classification
5.1.2.1	26/04/2021	Regulation Change
5.1.3.1	03/05/2021	Regulation Change

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
IARC: International Agency for Research on Cancer
ACGIH: American Conference of Governmental Industrial Hygienists
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit。
IDLH: Immediately Dangerous to Life or Health Concentrations
ES: Exposure Standard
OSF: Odour Safety Factor
NOAEL :No Observed Adverse Effect Level
LOAEL: Lowest Observed Adverse Effect Level
TLV: Threshold Limit Value
LOD: Limit Of Detection
OTV: Odour Threshold Value
BCF: BioConcentration Factors
BEI: Biological Exposure Index
AIIC: Australian Inventory of Industrial Chemicals
DSL: Domestic Substances List
NDSL: Non-Domestic Substances List
IECSC: Inventory of Existing Chemical Substance in China
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European List of Notified Chemical Substances
NLP: No-Longer Polymers
ENCS: Existing and New Chemical Substances Inventory
KECI: Korea Existing Chemicals Inventory
NZIoC: New Zealand Inventory of Chemicals
PICCS: Philippine Inventory of Chemicals and Chemical Substances
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory
INSQ: Inventario Nacional de Sustancias Químicas
NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

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TEL (+61 3) 9572 4700.

Safety Data Sheet
Hydrochloric Acid 15% H15

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Hydrochloric Acid 15% H15
Product code H015
Norway Pr. no. 17101
Denmark Pr. no. 1088965

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as an acidizing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield UK PLC
Victory House, Churchill Court
Manor Royal, Crawley
West Sussex RH10 9LU
+ 47 51577424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

Denmark	Poison Control Hotline (DK): +45 82 12 12 12
Netherlands	National Poisons Information Centre (NL): +31 30 274 88 88 (NB: this service is only available to health professionals)
Norway	Poison information centre: +47 22 59 13 00

2. Hazards Identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Health hazards

Skin corrosion/irritation	Category 1 Subcategory 1B
Serious eye damage/eye irritation	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Substances/mixtures corrosive to metal	Category 1

2.2 Label elements



Signal word
DANGER

Hazard statements
H314 - Causes severe skin burns and eye damage
H335 - May cause respiratory irritation
H290 - May be corrosive to metals

Precautionary Statements - EU (§28, 1272/2008)
P260 - Do not breathe dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTER or doctor/ physician
P406 - Store in corrosive resistant/ . container with a resistant inner liner

Supplementary precautionary statements
P234 - Keep only in original container
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P301 + P330 + P331 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting
P362 - Take off contaminated clothing and wash before reuse
P390 - Absorb spillage to prevent material damage
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/container in accordance with local regulations.

-

Contains
Hydrochloric acid

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%	Classification according to 67/548/EEC	Regulation (EC) No 1272/2008	REACH registration number
Hydrochloric acid	231-595-7	7647-01-0	15	-	Skin Corr. 1A (H314) STOT SE 3 (H335) Met. Corr.1 (H290) Note B	01-2119484862-27-xxxx

Comments
The product contains other ingredients which do not contribute to the overall classification.
Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations.

4. First aid measures

4.1 First Aid

Inhalation Move the exposed person to fresh air at once. If breathing is difficult, (trained personnel should) give oxygen. If not breathing, give artificial respiration. Seek medical attention at once.

Ingestion Do NOT induce vomiting. Get immediate medical attention. Rinse mouth. Risk of product entering the lungs on vomiting after ingestion. Never give anything by mouth to an unconscious person.

Skin contact Promptly wash contaminated skin with soap or mild detergent and water. Promptly remove clothing if soaked through and wash as above. Burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Chemical burns must be treated by a physician.

Eye contact Remove contact lenses. Immediately flush eyes with water for 15 minutes while holding eyelids open. Immediate medical attention is required.

4.2 Most important symptoms and effects, both acute and delayed

General advice Seek medical attention for all burns, regardless how minor they may seem. The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
The product itself does not burn, Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Contact with metals may evolve flammable hydrogen gas.

Hazardous combustion products
Fire or high temperatures create: Chlorine, chlorine oxides, hydrogen chloride.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Do not get on skin or clothing. Wash thoroughly after handling. Do not breathe vapours or spray mist. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment

Prevent further leakage or spillage if safe to do so. Dyke far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13).

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure Do not eat, drink or smoke when using this product Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Use only in area provided with appropriate exhaust ventilation. Keep airborne concentrations below exposure limits. Keep away from heat.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Avoid excessive heat for prolonged periods of time. Store away from incompatibles, Strong oxidising agents Alkalis Metals
Storage class	Corrosive storage.
Packaging materials	Use specially constructed containers only

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Chemical Name	EU OEL - Third List	Austria	Australia	Denmark
Hydrochloric acid	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	Not determined	5 ppm Ceiling 8 mg/m³ Ceiling
Chemical Name	**Malaysia**	**France**	**Germany**	**Hungary**
Hydrochloric acid	5 ppm Ceiling 7.5 mg/m³ Ceiling	5ppmSTEL 7.6mg/m³STEL	2 ppm TWA 3.0 mg/m³ TWA	8mg/m³TWA 16mg/m³STEL
Chemical Name	**New Zealand**	**Italy**	**Netherlands**	**Norway**
Hydrochloric acid	5 ppm Ceiling 7.5 mg/m³ Ceiling	Not determined	8 mg/m³ GW	5 ppm Ceiling; 7 mg/m³ Ceiling
Chemical Name	**Poland**	**Portugal**	**Romania**	**Russia**
Hydrochloric acid	10 mg/m³ STEL NDSCh	10 ppm STEL VLE-CD	10ppmSTEL	Acute dangerous

	5 mg/m³ TWA NDS	15 mg/m³ STEL VLE-CD 5 ppm TWA indicative limit value 8 mg/m³ TWA indicative limit value	15mg/m³STEL 5ppmTWA 8mg/m³TWA	substance 5 mg/m³ MAC
Chemical Name	**Spain**	**Switzerland**	**Turkey**	**UK**
Hydrochloric acid	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA VLA-ED 7.6 mg/m³ TWA VLA-ED	4 ppm STEL 6 mg/m³ STEL 2 ppm TWA MAK 3.0 mg/m³ TWA MAK	10 ppm STEL 15 mg/m³ STEL 5 ppm TWA 8 mg/m³ TWA	5 ppm STEL aerosol mist and gas 8 mg/m³ STEL aerosol mist and gas 1 ppm TWA aerosol mist and gas 2 mg/m³ TWA aerosol mist and gas

Derived No Effect Level (DNEL)

Short term exposure local effects

Hydrochloric acid

Inhalation 15 mg/m³

Long term exposure local effects

Hydrochloric acid

Inhalation 8 mg/m³

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure

Ensure adequate ventilation. Provide mechanical general and/or local exhaust ventilation to prevent release of vapor or mist into work environment.

Personal protective equipment

Eye protection Eye protection must conform to standard EN 166. Chemical splash goggles and face shield.

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training
Use protective gloves made of: Butyl Rubber Nitrile Viton
Break through time >480 minutes
Glove thickness 0.5 mm
Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection No personal respiratory protective equipment normally required, In case of insufficient ventilation wear suitable respiratory equipment, Respirator with combination filter for vapour/particulate (EN 141), Type E/P2, At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear suitable protective clothing, Eye wash and emergency shower must be available at the work place.

Hygiene measures Wash hands before eating, drinking or smoking, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odour	Pungent
Colour	Colourless
Odour threshold	No information available

Property	**Values**	**Remarks**
pH	< 2	
pH @ dilution		
Melting / freezing point	< 0 °C / 32 °F	
Boiling point/range	~100 °C / 212 °F	
Flash point	Not applicable	
Evaporation rate	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapour pressure	31.33 hPa (@ 20°C)	
Vapour density	1.267	
Specific gravity	1.1	@ 16 °C
Bulk density	No information available	
Relative density	1.161 - 1.19 g/cm³	@ 20 °C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	1 mPa.s (@ 20 °C)	
log Pow	Not determined	

Explosive properties	Not applicable
Oxidising properties	None known

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Corrosive. Corrosive to Metals. Contact with metals may evolve flammable hydrogen gas.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerisation
Hazardous polymerisation does not occur.

10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5 Incompatible materials

Strong oxidising agents. Alkalis. Metals.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Vapours are corrosive. After 24-36 hours, injured persons may develop serious shortness of breath and lung oedema. Vapours irritate the respiratory system, and may cause coughing and difficulties in breathing.

Eye contact Causes serious eye damage.

Skin contact Causes severe skin burns.

Ingestion Ingestion causes burns of the upper digestive and respiratory tracts.

Unknown acute toxicity Not applicable.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Hydrochloric acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Sensitisation This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	Inhalation. Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Category 3
Specific target organ toxicity - Repeated exposure	Not classified.
Target organ effects	Respiratory system.
Aspiration hazard	Not applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment. Large amounts will affect pH and harm aquatic organisms

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Hydrochloric acid	= 282 mg/L LC50 Gambusia affinis 96 h	No information available	No information available

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

12.4 Mobility in soil

Mobility
Soluble in water.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of as hazardous waste in compliance with local and national regulations.
Contaminated packaging	Empty containers should be transported/delivered using a registered waste carrier for local recycling or waste disposal.
EWC Waste Disposal No	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific Waste codes should be assigned by the user based on the application for which the product was used The following Waste Codes are only suggestions: EWC waste disposal No: 7131 Inorganic Acids 16 03 03 - inorganic wastes containing dangerous substances

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN 1789
UN No. (IMDG)	UN 1789
UN No. (ICAO)	UN 1789

14.2. UN proper shipping name
HYDROCHLORIC ACID SOLUTION 15%

14.3. Hazard class(es)

ADR/RID/ADN/ADG Hazard class	8
IMDG Hazard class	8
ICAO Hazard class/division	8

14.4 Packing group

ADR/RID/ADN/ADG Packing Group	III
IMDG Packing group	III

ICAO Packing group III



14.5 Environmental hazard
No

14.6 Special precautions

Hazard ID	80
EmS (IMDG)	F-A, S-B
Emergency Action Code (EAC)	2R
Tunnel restriction code	(E)

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Germany, Water Endangering Classes (VwVwS)	Hazardous to water/Class 1

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Hydrochloric acid
Schedule 6
Schedule 5

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

Dutch Mining Regulations: In accordance with Mining Regulations 9.2 and Chapter 4 of the Working Conditions Decree.

International inventories

USA, Toxic Substances Control Act inventory (TSCA)	Complies
European Union - EINECS and ELINCS	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Inventory - Japan - Existing and New Chemicals list	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korea (KECL)	Complies
Inventory - New Zealand - Inventory of Chemicals (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel
Supercedes date	19/Apr/2016
Revision date	31/Mar/2017
Version	3
This SDS has been revised in the following section(s)	All sections There have been changes with regard to classification.

Text of R phrases mentioned in Section 3
R34 - Causes burns
R37 - Irritating to respiratory system

Full text of H-Statements referred to under sections 2 and 3

H314 - Causes severe skin burns and eye damage
H335 - May cause respiratory irritation
H290 - May be corrosive to metals

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. J218
Version 5
Revision date 09-Aug-2018
Supersedes Date: 08-Sep-2017

Safety Data Sheet
Breaker J218

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Breaker J218
Product code J218

CAS No 7727-54-0
EC No 231-786-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

Croatia	01-23-48-342(for medical information) -Center for Poison

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2A
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Oxidizing Solids	Category 3

2.2 Label elements



Signal word
DANGER

Hazard Statements
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation
H272 - May intensify fire; oxidizer

Precautionary statements
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician
P280 - Wear protective gloves and eye/face protection

Supplementary precautionary statements
P220 - Keep away from clothing and other combustible materials
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P285 - In case of inadequate ventilation wear respiratory protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P330 - Rinse mouth
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/ container to an approved waste disposal plant
P410 - Protect from sunlight
P411 + P235 - Store at temperatures not exceeding 38 °C/ 100 °F. Keep cool
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable
P370 + P378 - In case of fire: Use water spray to extinguish

Contains
Diammonium peroxidisulphate

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Do not expose materials or their containers to moisture.

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Diammonium peroxidisulphate	231-786-5	7727-54-0	60-100

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get immediate medical attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Deluge with water. Other methods not effective.

Extinguishing media which must not be used for safety reasons
Dry chemical, carbon dioxide and other gas-filled extinguishers.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
May intensify fire; oxidizer.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors Sulfur oxides, Oxygen, Nitrogen oxides (NOx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 1Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Do not breathe dust. Avoid contact with the skin and the eyes.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Spilled oxidizer must be removed immediately and isolated for disposal. Isolated material must be monitored for signs of decomposition (fuming/smoking). If spilled material is wet, dissolve with large quantity of water. All disposals must be carried out at the earliest opportunity and in accordance with local /regional /national /international regulations. Take up mechanically and collect in suitable container for disposal. Use non-sparking tools and equipment. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety practice. Follow procedures for safe handling of oxidizers. Do not expose materials or their containers to moisture. Keep away from open flames, hot surfaces and sources of ignition. Avoid handling causing generation of dust. Avoid contact with skin and eyes. May produce an allergic reaction.

Hygiene Measures
Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing When using do not smoke, eat or drink.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Ensure adequate ventilation. Keep airborne concentrations below exposure limits.

Storage precautions Oxidizers must be stored separately from all other materials. Keep containers tightly closed in a dry, cool and well-ventilated place Protect from moisture Keep away from direct sunlight. Keep at a temperature not exceeding 110 °F /43 °C Keep away from open flames,

hot surfaces and sources of ignition Oxidizing material - Keep away from flammable and combustible materials. Store away from incompatible materials Oxidizing agents Reducing Agents Acids

Storage class Oxidiser storage.

Packaging materials Use specially constructed containers only.

Packaging materials to be avoided Containers made of MONEL, copper, brass, or iron.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits Control as an ACGIH particulate not otherwise specified (PNOS): 10 mg/m³ (Inhalable); 3 mg/m³ (Respirable) and an OSHA particulate not otherwise regulated (PNOR): 15 mg/m³ (Total); 5 mg/m³ (Respirable).

Component Information

Chemical Name	Arabic	Australia	Egypt
Diammonium peroxidisulphate	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Diammonium peroxidisulphate	Not determined	0.1 mg/m³ TWA	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Diammonium peroxidisulphate	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Diammonium peroxidisulphate	0.1 mg/m³ TWA	Not determined	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Diammonium peroxidisulphate	Not determined	Not determined	Not determined

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will

vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Tightly fitting safety goggles
Hand protection	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Do not wear rings, watches or anything similar which can retain the product and may give rise to skin conditions. Wear protective butyl rubber gloves Break through time >480 minutes Glove thickness 2 mm Frequent change is advisable
Respiratory protection	Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust) Effective dust mask. Half mask with a particle filter P2 (European Norm EN 143 = former DIN 3181) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Crystalline
Odor	Odorless
Color	White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	4 - 5 @10 g/l	
Melting / freezing point	120 °C / 249 °F	
Boiling point/range	No information available	
Flash point		
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	

Vapor density	No information available	
Specific gravity	No information available	
Bulk density	1000 Kg/m³	
Relative density	1.26 g/cm³	@ 20°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	120 °C / 249 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	Strong oxidizer. Contact with other material may cause fire

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

This product is a strong oxidizer and reacts violently with combustibles and reducing agents.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid contamination. Avoid dust formation. Protect from moisture. Keep away from direct sunlight. Keep at a temperature not exceeding 110 °F /43 °C. Keep away from open flames, hot surfaces and sources of ignition. Oxidizing material - Keep away from flammable and combustible materials.

10.5 Incompatible materials

Do not mix oxidizers of any concentration with other oxidizing agents, reducing agents, flammable or combustible liquids or solids, acids, most metals and heavy metals, oxygen scavengers, corrosion inhibitors, surfactants, gelling agents, fluid-loss additives, cross linkers, solvents, foaming agents, clay control agents, or any chemical not specifically mentioned as being compatible with the specific oxidizer.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information May produce an allergic reaction.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation of respiratory tract.

Eye contact Causes serious eye irritation.

Skin contact Irritating to skin. May cause an allergic skin reaction.

Ingestion Harmful if swallowed.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diammonium peroxidisulphate	700-742 mg/kg (Rat)	> 2000 mg/kg (Rat)	No data available

Sensitization May cause sensitization by inhalation and skin contact.

Mutagenic effects This substance has no evidence of mutagenic properties.

Carcinogenicity This substance has no evidence of carcinogenic properties.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Inhalation. Skin contact. Eye contact.

Routes of entry Inhalation. Ingestion. Skin contact.

Specific target organ toxicity - Single exposure Category 3

Specific target organ toxicity - Repeated exposure Not classified.

Target organ effects Respiratory system.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Diammonium peroxidisulphate	= 76.3 mg/L LC50 Oncorhynchus mykiss 96 h	= 136 mg/l EC50 Phaenodactylum tricornutum 72h	= 120 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

Does not bioaccumulate.

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations.

Contaminated packaging Do not re-use empty containers. Dispose of contents/container to an approved waste disposal plant.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN 1444
UN No. (IMDG/ANTAQ)	UN 1444
UN No. (ICAO/ANAC)	UN 1444

14.2. UN proper shipping name
AMMONIUM PERSULFATE,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	5.1
IMDG/ANTAQ Hazard class	5.1
ICAO/ANAC Hazard class/division	5.1

14.4 Packing group

ADR/RID/ADN/ADG Packing group	PG III
IMDG/ANTAQ Packing group	PG III
ICAO/ANAC Packing group	PG III



14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions

Hazard identification no (ADR)	50
EmS (IMDG)	F-A, S-Q
Tunnel restriction code	(E)
Hazchem code ADG	1Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Not applicable

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Diammonium peroxidisulphate
Schedule 6

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	08-Sep-2017
Revision date	09-Aug-2018
Version	5
This SDS has been revised in the following section(s)	2, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2
Flammability	1
Physical hazard	2
PPE	X

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SDS no. J475
Version 4
Revision date 31-Aug-2017
Supersedes Date: 21-Aug-2017

Safety Data Sheet
EB-Clean* J475 Breaker

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name EB-Clean* J475 Breaker
Product code J475

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Specific target organ toxicity - Single exposure	Category 3

Environmental hazards Not classified

Physical Hazards

Oxidizing Solids	Category 3

2.2 Label elements



Signal word
DANGER

Hazard Statements
H302 - Harmful if swallowed
H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation
H272 - May intensify fire; oxidizer

Precautionary statements
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P370 + P378 - In case of fire: Use water spray to extinguish
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P410 - Protect from sunlight
P411 - Store at temperatures not exceeding 38 °C/ 100 °F

Supplementary precautionary statements
P221 - Take any precaution to avoid mixing with combustibles
P264 - Wash face, hands and any exposed skin thoroughly after handling
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P285 - In case of inadequate ventilation wear respiratory protection
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P330 - Rinse mouth
P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention
P337 + P313 - If eye irritation persists: Get medical advice/attention
P362 - Take off contaminated clothing and wash before reuse
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Diammonium peroxodisulphate

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Diammonium peroxodisulphate	231-786-5	7727-54-0	60 - 100

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove to fresh air. If not breathing give artificial respiration, preferably mouth-to-mouth. If breathing is difficult give oxygen. Get immediate medical attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Never give anything by mouth to an unconscious person. Get immediate medical attention.

Skin contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention.

Eye Contact Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. Get immediate medical attention.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Deluge with water. Other methods not effective.

Extinguishing media which must not be used for safety reasons
Dry chemical, carbon dioxide and other gas-filled extinguishers.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
May intensify fire; oxidizer.

Hazardous combustion products
Heating or fire can release toxic gas Sulphur oxides, Oxygen, Nitrogen.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 1Z

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Do not breathe dust. Avoid contact with the skin and the eyes.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading.

Methods for cleaning up
Spilled oxidizer must be removed immediately and isolated for disposal. Isolated material must be monitored for signs of decomposition (fuming/smoking). If spilled material is wet, dissolve with large quantity of water. All disposals must be carried out at the earliest opportunity and in accordance with local /regional /national /international regulations. Take up mechanically and collect in suitable container for disposal. Take precautionary measures against static discharges. Use non-sparking tools and equipment. Avoid dust formation. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Do not handle until all safety precautions have been read and understood. Handle in accordance with good industrial hygiene and safety practice. Follow procedures for safe handling of oxidizers. Do not expose materials or their containers to moisture. Keep

away from open flames, hot surfaces and sources of ignition. Avoid handling causing generation of dust. Avoid breathing dust; if exposed to high dust concentration, leave area immediately. Avoid contact with skin and eyes. Persons susceptible to allergic reactions should not handle this product.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Provide appropriate exhaust ventilation at places where dust is formed. Keep away from heat, sparks, and flame. Keep containers in cool areas out of direct sunlight and away from combustibles.

Storage precautions Oxidizers must be stored separately from all other materials. Keep containers tightly closed in a dry, cool and well-ventilated place Protect from moisture Keep away from direct sunlight. Keep at a temperature not exceeding 100°F /38 °C Keep away from open flames,

hot surfaces and sources of ignition Oxidizing material - Keep away from flammable and combustible materials. Store away from incompatibles, Strong reducing agents Strong bases Reducing Agents Heavy metals

Packaging materials Use specially constructed containers only. Coated (epoxy phenolic) steel drum or high density polyethylene (HDPE) can

Packaging materials to be avoided Containers made of MONEL, copper, brass, or iron.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.
No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Diammonium peroxodisulphate	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Diammonium peroxodisulphate	Not determined	0.1 mg/m^3 TWA	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Diammonium peroxodisulphate	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Diammonium peroxodisulphate	0.1 mg/m^3 TWA	Not determined	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Diammonium peroxodisulphate	Not determined	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Eye protection must conform to standard EN 166 Wear dust resistant safety goggles where there is a danger of eye contact.
Hand protection	Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Do not wear rings, watches or anything similar which can retain the product and may give rise to skin conditions. Impervious gloves made of: polyvinyl alcohol or nitrile-butyl rubber gloves Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	Sweet
Color	White
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	No information available	
pH @ dilution	6.5 - 8	@ 10g/l
Melting / freezing point	Decomposes	
Boiling point/range	No information available	
Flash point	> 93 °C / > 200 °F	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.8	@20 °C
Bulk density	1150 kg/m³	
Relative density	No information available	
Water solubility	10 - 20 g/l	@ 20 °C
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	120 °C/ 248 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	

log Pow	No information available
Explosive properties	No information available
Oxidizing properties	Oxidizer. Contact with other material may cause fire

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

This product is a strong oxidizer and reacts violently with combustibles and reducing agents.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Protect from moisture. Avoid dust formation. Avoid contamination. Keep away from direct sunlight.

10.5 Incompatible materials

Do not mix oxidizers of any concentration with other oxidizing agents, reducing agents, flammable or combustible liquids or solids, acids, most metals and heavy metals, oxygen scavengers, corrosion inhibitors, surfactants, gelling agents, fluid-loss additives, cross linkers, solvents, foaming agents, clay control agents, or any chemical not specifically mentioned as being compatible with the specific oxidizer.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information	May produce an allergic reaction.
Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause irritation of respiratory tract. May cause drowsiness or dizziness.
Eye contact	Causes serious eye irritation.
Skin contact	Irritating to skin. May cause an allergic skin reaction.

Ingestion Harmful if swallowed.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Diammonium peroxodisulphate	= 495 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	= 520 mg/L (Rat) 1 h

Sensitization May cause sensitization by inhalation and skin contact.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of Exposure Inhalation. Skin contact. Eye contact. Ingestion.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Category 3

Specific target organ toxicity - Repeated exposure Not classified.

Target organ effects Respiratory system.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Diammonium peroxodisulphate	= 323 mg/L LC50 Poecilia reticulata 96 h = 76.3 mg/L LC50 Oncorhynchus mykiss 96 h = 103 mg/L LC50 Lepomis macrochirus 96 h	No information available	= 120 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

Not Applicable - Inorganic chemical.

Chemical Name	Persistence and degradability
Diammonium peroxodisulphate	Hydrolyzes

12.3 Bioaccumulative potential

Not Applicable - Inorganic chemical.

Chemical Name	Bioaccumulation
Diammonium peroxodisulphate	Product does not bioaccumulate due to reaction with water

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Chemical Name	Mobility
Diammonium peroxodisulphate	Easily soluble

Mobility in soil
No information available.

Chemical Name	Mobility in soil
Diammonium peroxodisulphate	Not expected to adsorb on soil

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of as special waste in compliance with local and national regulations.

Contaminated packaging Do not re-use empty containers. Dispose of contents/container to an approved waste disposal plant.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN1444
UN No. (IMDG/ANTAQ)	UN1444
UN No. (ICAO/ANAC)	UN1444

14.2. UN proper shipping name
AMMONIUM PERSULFATE,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	5.1
IMDG/ANTAQ Hazard class	5.1
ICAO/ANAC Hazard class/division	5.1

14.4 Packing group

ADR/RID/ADN/ADG Packing group	III
IMDG/ANTAQ Packing group	III
ICAO/ANAC Packing group	III



14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions

EmS (IMDG)	F-A, S-Q
Tunnel restriction code	E
Hazchem code ADG	1Z

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Diammonium peroxodisulphate
Schedule 6

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Anne Karin (Anka) Fosse
Supersedes Date:	21-Aug-2017
Revision date	31-Aug-2017
Version	4
This SDS has been revised in the following section(s)	8. EXPOSURE CONTROLS / PERSONAL PROTECTION No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2*
Flammability	1
Physical hazard	1
PPE	X

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SDS no. J580
Version 4
Revision date 07-Aug-2018
Supersedes Date: 21-Apr-2017

Safety Data Sheet
Water Gelling Agent J580

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Water Gelling Agent J580
Product code J580

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Suspended dust may present a dust explosion hazard

Australian statement of hazardous/dangerous nature

Classified as Non-Hazardous according to the criteria of NOHSC.
NON-HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation — If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion — Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact — Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye Contact — Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice — The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation — Please see Section 11. Toxicological Information for further information.

Ingestion — Please see Section 11. Toxicological Information for further information.

Skin contact — Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Dust may form explosive mixture in air.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Extinguish all ignition sources. Avoid sparks, flames, heat and smoking.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Cover powder spill with plastic sheet or tarp to minimize spreading. Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Take precautionary measures against static discharges. Sweep up and shovel into suitable containers for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Material becomes slippery when wet. Use caution if wet.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits. Take precautionary measures against static discharges.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Keep away from open flames, hot surfaces and sources of ignition Protect from moisture Avoid contact with: Oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits NUI = Nuisance dust, TWA 4mg/m^3 Respirable Dust, 10mg/m^3 Total Dust.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Mechanical ventilation or local exhaust ventilation is required. Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against powders and dusts Safety glasses with side-shields Tightly fitting safety goggles
Hand protection	Wear gloves according to EN 374 to protect against skin effects from powders Use protective gloves made of: Neoprene Nitrile Rubber Frequent change is advisable
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	Slight
Color	Light tan
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	Not applicable	
pH @ dilution	5.5 - 7.5 (10g/L)	
Melting / freezing point	> 180 °C / 356 °F	
Boiling point/range	No information available	
Flash point	No information available	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.40 - 1.45	
Bulk density	800 kg/m³	
Relative density	No information available	
Water solubility	Dispersible	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	> 242 °C / 468 °F	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties Suspended dust may present a dust explosion hazard
Oxidizing properties None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments

The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid dust formation. Protect from moisture.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.
Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.

Routes of exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	Inhalation.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	Not applicable.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

Listed on PLONOR list of OSPAR The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

Product is biodegradable.

12.3 Bioaccumulative potential

The product does not contain any substances expected to be bioaccumulating.

12.4 Mobility

Mobility
Dispersible in water.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

No poisons schedule number allocated

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	21-Apr-2017
Revision date	07-Aug-2018
Version	4
This SDS has been revised in the following section(s)	1, 2, 7, 8, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	D

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SDS no. J604
Version 3
Revision date 22-Feb-2019
Supersedes Date: 30-Sep-2015

Safety Data Sheet
Crosslinker J604

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Crosslinker J604
Product code J604

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Acute toxicity - Oral	Category 4
Specific target organ toxicity - Repeated exposure	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P330 - Rinse mouth

Supplementary precautionary statements
P314 - Get medical advice/attention if you feel unwell
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable

Contains
Ethylene Glycol

Sodium Tetraborate Decahydrate

but-2-enedioic acid

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Ethylene Glycol	203-473-3	107-21-1	10-30
Sodium Tetraborate Decahydrate	215-540-4	1303-96-4	1-<5
but-2-enedioic acid	203-743-0	110-17-8	1-<3

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Seek medical attention if irritation occurs.

Skin contact Wash off immediately with soap and plenty of water. Remove contaminated clothing and shoes. Seek medical attention if irritation occurs.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin, eyes and inhalation of vapors. Wash thoroughly after handling. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13). After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Avoid spills and splashing during use. Do not breathe vapors or spray mist.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Do not eat, drink or smoke when using this product Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store in original container. Avoid heat, flames and other sources of ignition. Keep away from direct sunlight. Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits	No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Ethylene Glycol	Not determined	40ppmSTELvapour 104mg/m³STELvapour 10mg/m³TWAparticulate 20ppmTWAvapour 52mg/m³TWAvapour	39.4 ppm Ceiling 100 mg/m³ Ceiling
Sodium Tetraborate Decahydrate	Not determined	5mg/m³TWA 1mg/m³TWA	5 mg/m³ TWA
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Ethylene Glycol	Not determined	100 mg/m³ STEL	Not determined
Sodium Tetraborate Decahydrate	Not determined	5 mg/m³ TWA	Not determined
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Ethylene Glycol	5 mg/m³ MAC	125 mg/m³ TWA 50.0 ppm TWA 100 mg/m³ STEL	50 ppm Ceiling mist and vapour 127 mg/m³ Ceiling mist and vapour
Sodium Tetraborate Decahydrate	Not determined	Not determined	5 mg/m³ TWA
but-2-enedioic acid	Not determined	Not determined	Not determined
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Ethylene Glycol	39.4 ppm Ceiling aerosol 100 mg/m³ Ceiling aerosol	Not determined	10 mg/m³ STEL 5 mg/m³ TWA
Sodium Tetraborate Decahydrate	5 mg/m³ TWA	Not determined	2 mg/m³ MAC
but-2-enedioic acid	Not determined	Not determined	5 mg/m³ MAC
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Ethylene Glycol	Not determined	10 mg/m³ TWA 60 mg/m³ TWA 20 mg/m³ STEL 125 mg/m³ STEL	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA 52 mg/m³ TWA
Sodium Tetraborate Decahydrate	5 mg/m³ TWA	Not determined	Not determined
but-2-enedioic acid	Not determined	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Keep airborne concentrations below exposure limits Ensure adequate ventilation, especially in confined areas

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly fitting safety goggles Safety glasses with side-shields

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Wear chemical resistant gloves such as nitrile or neoprene. Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Respirator with a vapor filter (EN 141) Use respirator with organic vapor protection (A, brown) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Opaque
Odor	Odorless
Color	Beige or Milky white
Odor threshold	Not applicable

Property	Values	Remarks
pH	6.5 - 7.2	
pH @ dilution	No information available	
Melting / freezing point	No information available	
Boiling point/range	No information available	
Flash point	Does not flash	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.27 - 1.37	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Miscible with water.	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	None known.

9.2 Other information

Pour point	< -15 °C / < 5 °F
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Keep away from direct sunlight.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of vapors in high concentration may cause irritation of respiratory system. Harmful: danger of serious damage to health by prolonged exposure through inhalation.

Eye contact May cause slight irritation.

Skin contact Prolonged contact may cause redness and irritation.

Ingestion Harmful if swallowed. May cause adverse kidney effects. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethylene Glycol	= 4700 mg/kg (Rat)	= 9530 µL/kg (Rabbit) = 10600 mg/kg (Rat)	No data available
Sodium Tetraborate Decahydrate	LD50 = 2660 mg/kg (Rat)	> 10000 mg/kg (Rabbit)	> 2 mg/m³ (Rat) 4 h
but-2-enedioic acid	= 9300 mg/kg (Rat)	> 20000 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	Contains a known or suspected reproductive toxin.
Routes of Exposure	Inhalation. Skin contact. Eye contact. Ingestion.
Routes of entry	Inhalation. Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Category 2.
Target organ effects	Kidney.
Aspiration hazard	Not classified.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Ethylene Glycol	= 16000 mg/L LC50 Poecilia reticulata 96 h 40000 - 60000 mg/L LC50 Pimephales promelas 96 h = 40761 mg/L LC50 Oncorhynchus mykiss 96 h = 27540 mg/L LC50 Lepomis macrochirus 96 h 14 - 18 mL/L LC50 Oncorhynchus mykiss 96 h = 41000 mg/L LC50 Oncorhynchus mykiss 96 h	6500 - 13000 mg/L EC50 Pseudokirchneriella subcapitata 96 h	= 46300 mg/L EC50 Daphnia magna 48 h
Sodium Tetraborate Decahydrate	340 mg/L LC50 (Limanda limanda) = 96 h	2.6 - 21.8	1085 - 1402 mg/L LC50 (Daphnia magna) = 48 h
but-2-enedioic acid	= 245 mg/L LC50 Brachydanio rerio 48 h	= 41 mg/L EC50 Desmodesmus subspicatus 72 h	= 73.6 mg/L EC50 Daphnia magna 24 h 204 - 220 mg/L EC50 Daphnia magna 48 h

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility

Mobility
No information available.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

Not regulated

14.2. UN proper shipping name

The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated

IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Ethylene Glycol
Schedule 6
Schedule 5
Sodium Tetraborate Decahydrate
Schedule 4
Schedule 5

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Does not comply
Japan (ENCS)	Does not comply
China (IECSC)	Does not comply
Australia (AICS)	Complies
Korean (KECL)	Does not comply
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals)
Supersedes Date:	30-Sep-2015

Revision date	22-Feb-2019
Version	3
This SDS has been revised in the following section(s)	All sections Updated according to GHS/CLP.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	2*
Flammability	1
Physical hazard	0
PPE	X

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SDS no. J711
Version 1
Revision date 21-Oct-2020
Supersedes Date: None

Safety Data Sheet
Dry High Viscosity Friction Reducer J711

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Dry High Viscosity Friction Reducer J711
Product code J711
Country Limitations This SDS is not for use in the European Union (EU).

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Friction reducer.

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield UK PLC
Schlumberger House, Buckingham Gate
Gatwick Airport
West Sussex RH6 0NZ

+ 47 51577424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria
Combustible dust

3. Composition/information on Ingredients

3.1 Substances

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

3.2 Mixtures

Not applicable

4. First Aid Measures

4.1 First aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Ingestion	Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.
Skin contact	Wash skin thoroughly with soap and water. Get medical attention if irritation persists.
Eye Contact	Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice	The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.
Symptoms	
Inhalation	Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
Do not use water jet.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Suspended dust may present a dust explosion hazard.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors Carbon oxides (COx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Keep away from combustible material. Avoid contact with heat, sparks, open flame, and static discharge. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Cover powder spill with plastic sheet or tarp to minimize spreading.

Methods for cleaning up
Avoid dust formation. Do not dry sweep dust. Wet dust with water before sweeping or use a vacuum to collect dust. Take precautionary measures against static discharges. Use non-sparkling tools and equipment. Material becomes slippery when wet. Use caution if wet. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid handling causing generation of dust. All equipment used when handling the product must be grounded. Material becomes slippery when wet. Use caution if wet. Avoid breathing dust; if exposed to high dust concentration, leave area immediately. Fine dust dispersed in air may ignite. Take precautionary measures against static discharges.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Provide appropriate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits. Take precautionary measures against static discharges. Ensure all equipment is electrically grounded before beginning transfer operations.
Storage precautions	Keep container/package tightly closed and in a well-ventilated place. Keep away from open flames, hot surfaces and sources of ignition Avoid contact with: Strong oxidizing agents Strong acids Strong bases
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits Contains no substances with occupational exposure limit values

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical

hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against dusts Tightly fitting safety goggles Safety glasses with side-shields
Hand protection	Wear gloves according to EN 374 to protect against skin effects from powders Wear chemical resistant gloves such as nitrile or neoprene. Frequent change is advisable
Respiratory protection	No personal respiratory protective equipment normally required In case of insufficient ventilation wear suitable respiratory equipment Half mask with a particle filter P2 (BS EN 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.
Hygiene Measures	Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Odor	No information available
Color	Off-white
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	7 - 8	
pH @ dilution	No information available	
Melting / freezing point	> 300◦C / 572◦F	
Boiling point/range	No information available	
Flash point	No information available	
Evaporation rate	Not applicable	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	

Vapor pressure	No information available
Vapor density	No information available
Specific gravity	0.8
Bulk density	No information available
Relative density	No information available
Water solubility	Soluble in water
Solubility in other solvents	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Kinematic viscosity	No information available
Dynamic viscosity	No information available
log Pow	No information available

Explosive properties	Suspended dust may present a dust explosion hazard
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation. Avoid heat, flames and other sources of ignition.

10.5 Incompatible materials

Strong oxidizing agents. Strong acids. Strong bases.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough.
Eye contact	Dust may cause mechanical irritation.
Skin contact	Repeated exposure may cause skin dryness or cracking.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of Exposure	Inhalation. Skin contact. Eye contact.
Routes of entry	Inhalation.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	No information available.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility

Mobility
Soluble in water.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

This SDS is not for use in the European Union (EU).

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Poh Yue Cheong
Revision date	21-Oct-2020
Version	1
This SDS has been revised in the following section(s)	New issue.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	E

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SDS no. L065
Version 4
Revision date 18-Oct-2016
Supersedes date 11-Dec-2014

Safety Data Sheet
Scale Inhibitor L065

1. Identification of the substance/preparation and of the Company/undertaking

1.1 Product identifier

Product name Scale Inhibitor L065
Product code L065

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Scale Inhibitor. Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518, Canada 001 613 996 6666

2. Hazards identification

2.1 Classification of the substance or mixture

Classification according to (EC) No. 1272/2008

Health hazards

Acute oral toxicity	Category 4
Specific target organ toxicity (repeated exposure)	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard statements
H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary Statements - EU (§28, 1272/2008)
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with local regulations.

Supplementary precautionary statements
P314 - Get medical advice/attention if you feel unwell

-

Contains
Ethylene glycol

Calcium Chloride

2,2''-oxydiethanol (impurity)

Sodium hydroxide (impurity)

2.3 Other data

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

Not Applicable

3.2 Mixtures

Component	EC-No.	CAS-No	Weight % - range	Classification (67/548)	Classification (Reg. 1272/2008)	REACH registration number
Ethylene glycol	203-473-3	107-21-1	10-30	Xn; R48/22	Acute Tox. 4 (H302)	No data available

					STOT RE. 2(H373)	
Calcium Chloride	233-140-8	10043-52-4	1 - 5	Xi; R36	Eye Irrit. 2 (H319)	No data available
2,2''-oxydiethanol (impurity)	203-872-2	111-46-6	0.1 - 1.0	Xn; R22, R48/22	Acute Tox. 4 (H302) STOT RE. 2 (H373)	01-2119457857-21-xxxx
Sodium hydroxide (impurity)	215-185-5	1310-73-2	<1	C;R35	Skin Corr. 1A (H314)	No data available

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First aid measures

4.1 First-Aid Measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if irritation persists.

Eye contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses. Get medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Main symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which shall not be used for safety reasons
None known.

5.2 Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and materials for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing. Do not eat, drink or smoke when using this product.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place. Avoid extreme temperatures. Avoid heat, flames and other sources of ignition. Store away from incompatibles, Strong oxidizing agents

Storage class Chemical storage.

Packaging material Use specially constructed containers only.

7.3 Specific end uses

See Section 1.2.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits No biological limit allocated

Component	EU OEL	Austria	Australia	Denmark
Ethylene glycol	40 ppm STEL 104 mg/m³ STEL 20 ppm TWA 52 mg/m³ TWA Possibility of significant uptake through the skin	20 ppm STEL 52 mg/m³ STEL 10 ppm TWA 26 mg/m³ TWA	40ppmSTELvapour 104mg/m³STELvapour 10mg/m³TWAparticulate 20ppmTWAvapour 52mg/m³TWAvapour skin notation	10 ppm TWA 26 mg/m³ TWA 10 mg/m³ TWA Potential for cutaneous absorption
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	Not determined	40 ppm STEL 176 mg/m³ STEL 10 ppm TWA 44 mg/m³ TWA	23ppmTWA 100mg/m³TWA	2.5 ppm TWA 11 mg/m³ TWA
Sodium hydroxide (impurity)	Not determined	4 mg/m³ STEL inhalable fraction 2 mg/m³ TWA inhalable fraction	Not determined	2 mg/m³ Ceiling

Component	Malaysia	France	Germany	Hungary
Ethylene glycol	39.4 ppm Ceiling aerosol 100 mg/m³ Ceiling aerosol	40ppmSTEL 104mg/m³STEL 20 ppmTWA 52 mg/m³TWA	10 ppm TWA 26 mg/m³ TWA	52mg/m³TWA 104mg/m³STEL
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	Not determined	Not determined	10 ppm TWA 44 mg/m³ TWA	Not determined
Sodium hydroxide (impurity)	2 mg/m³ Ceiling	2 mg/m³TWA	Not determined	2mg/m³TWA 2mg/m³STEL

Component	New Zealand	Italy	Netherlands	Norway
Ethylene glycol	50 ppm Ceiling mist and vapour 127 mg/m³ Ceiling mist and vapour	Not determined	104mg/m³STEL 52 mg/m³ 10 mg/m³	20 mg/m³ TWA dust 52 ppm TWA total dust and vapor 52 mg/m³ TWA 52 mg/m³ STEL dust 20 ppm STEL Skin
Calcium Chloride	Not Determined	Not determined	Not determined	Not determined
2,2"-oxydiethanol (impurity)	23 ppm TWA 101 mg/m³ TWA	Not determined	Not determined	Not determined
Sodium hydroxide (impurity)	2 mg/m³ Ceiling	Not determined	Not determined	2 mg/m³ Ceiling

Component	Poland	Portugal	Romania	Russia
Ethylene glycol	50 mg/m³ STEL NDSCh 15 mg/m³ TWA NDS	Skin 40 ppm STEL VLE-CD 104 mg/m³ STEL VLE-CD 20 ppm TWA indicative limit value 52 mg/m³ TWA indicative limit value	40ppmSTEL 104mg/m³STEL 20ppmTWA 52mg/m³TWA	10 mg/m³ STEL 2308 aerosol and vapor 5 mg/m³ TWA 2308
Calcium Chloride	Not determined	Not determined	Not determined	2 mg/m³ MAC Skin
2,2"-oxydiethanol (impurity)	10 mg/m³ TWA NDS	Not determined	184ppmSTEL 800mg/m³STEL 115ppmTWA	10 mg/m³ MAC (aerosol and vapor)

			500mg/m³TWA	
Sodium hydroxide (impurity)	1 mg/m³ STEL NDSCh 0.5 mg/m³ TWA NDS	Not determined	Not determined	Not determined
Component	**Spain**	**Switzerland**	**Turkey**	**UK**
Ethylene glycol	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA VLA-ED 52 mg/m³ TWA VLA-ED	20 ppm STEL 52 mg/m³ STEL Skin 10 ppm TWA MAK 26 mg/m³ TWA MAK	40 ppm STEL 104 mg/m³ STEL Skin 20 ppm TWA 52 mg/m³ TWA	40 ppm STEL vapour 104 mg/m³ STEL vapour 30 mg/m³ STEL calculated particulate Skin 10 mg/m³ TWA particulates 20 ppm TWA vapour 52 mg/m³ TWA vapour
Calcium Chloride	Not determined	Not determined	Not determined	Not determined
2,2''-oxydiethanol (impurity)	Not determined	40 ppm STEL (KZW): 176 mg/m³ STEL (KZW)	Not determined	69 ppm STEL calculated 303 mg/m³ STEL calculated 23 ppm TWA 101 mg/m³ TWA
Sodium hydroxide (impurity)	2 mg/m³ STEL	2 mg/m³ STEL inhalable dust 2 mg/m³ TWA MAK	Not determined	2 mg/m³ STEL

Derived No Effect Level (DNEL)

Long term exposure systemic effects

2,2''-oxydiethanol (impurity)

Dermal	106 mg/kg bw/day
Inhalation	60 mg/m³

Predicted No Effect Concentration (PNEC)

2,2''-oxydiethanol (impurity)

Fresh water	10 mg/l
Sea water	1 mg/l
Fresh water sediment	20.9 mg/kg sediment dw
Sea sediment	2.09 mg/kg sediment dw
Soil	1.53 mg/kg soil dw
Impact on sewage treatment	199.5 mg/L
Intermittent release	10 mg/l

Sodium hydroxide (impurity)

Impact on sewage treatment	1503

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering measures to reduce exposure
Ensure adequate ventilation. Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection	Tightly fitting safety goggles. Safety glasses with side-shields.
Hand protection	Use protective gloves made of:, polyvinyl alcohol or nitrile-butyl rubber gloves, Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment, Respirator with combination filter for vapour/particulate (EN 141), At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.
Skin and body protection	Wear suitable protective clothing, Eye wash and emergency shower must be available at

the work place.

Hygiene measures Wash hands before breaks and immediately after handling the product, Remove and wash contaminated clothing before re-use.



9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Aqueous solution
Odor	Mild
Color	Pale yellow
Odor threshold	Not applicable

Property	Values	Remarks
pH	7.8 - 8.8	
pH @ dilution		
Melting/freezing point	-50 °C / -58 °F	
Boiling point/range	100 °C / 212 °F	
Flash point	> 100 °C / 212 °F	PMCC
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not Applicable	
Flammability Limits in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	7 kPa	@ 20 °C
Vapor density	No information available	
Specific gravity	1.2	@15.6 °C
Bulk density	No information available	
Relative density	1.2	@ 15.6°C.
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	5 mm2/s	@ 40 °C
Dynamic viscosity	6 mPa s	@ 38 °C
Log Pow	No information available	

Explosive properties	Not Applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

10. Stability and reactivity

10.1 Reactivity

Stable under recommended storage conditions.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid heat, flames and other sources of ignition. Avoid extreme temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of vapors in high concentration may cause irritation of respiratory system.

Eye contact May cause slight irritation.

Skin contact Prolonged contact may cause redness and irritation. Components of the product may be absorbed into the body through the skin.

Ingestion Harmful if swallowed. May cause adverse cardiac effects, blood disturbances, and metabolic acidosis. May cause damage to organs through prolonged or repeated exposure.

Unknown acute toxicity Not Applicable.

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Ethylene glycol	= 4700 mg/kg (Rat)	= 9530 µL/kg (Rabbit) = 10600 mg/kg (Rat)	No data available
Calcium Chloride	= 1000 mg/kg (Rat)	= 2630 mg/kg (Rat)	No data available
2,2"-oxydiethanol (impurity)	= 12565 mg/kg (Rat)	= 11890 mg/kg (Rabbit)	No data available
Sodium hydroxide (impurity)	No data available	= 1350 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Skin contact. Ingestion.
Routes of entry	Ingestion. Skin contact. Skin absorption.
Specific target organ toxicity (single exposure)	Not classified
Specific target organ toxicity (repeated exposure)	Category 2.
Target organ effects	Kidney.
Aspiration hazard	Not Applicable.

12. Ecological information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

Component	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Ethylene glycol	= 41000 mg/L LC50 Oncorhynchus mykiss 96 h 14 - 18 mL/L LC50 Oncorhynchus mykiss 96 h = 27540 mg/L LC50 Lepomis macrochirus 96 h = 40761 mg/L LC50 Oncorhynchus mykiss 96 h 40000 - 60000 mg/L LC50 Pimephales promelas 96 h = 16000 mg/L LC50 Poecilia reticulata 96 h	6500 - 13000 mg/L EC50 Pseudokirchneriella subcapitata 96 h	= 46300 mg/L EC50 Daphnia magna 48 h
Calcium Chloride	= 10650 mg/L LC50 Lepomis macrochirus 96 h	No information available	= 2400 mg/L LC50 Daphnia magna 48 h
2,2''-oxydiethanol (impurity)	= 75200 mg/L LC50 Pimephales promelas 96 h	No information available	= 84000 mg/L EC50 Daphnia magna 48 h
Sodium hydroxide (impurity)	= 45.4 mg/L LC50 Oncorhynchus mykiss 96 h	No information available	No information available

12.2 Persistence and degradability

No product level data available.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility in soil

Mobility
The product is water soluble, and may spread in water systems.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues / unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.
EWC Waste disposal No.	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used. The following Waste Codes are only suggestions: EWC waste disposal No: 16 05 08 - discarded organic chemicals consisting of or containing dangerous substances.

14. Transport information

14.1 UN Number
Not regulated

14.2 Proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG Hazard class	Not regulated
ICAO Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG Packing group	Not regulated
ICAO Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Ethylene glycol
Schedule 6
Schedule 5
2,2''-oxydiethanol (impurity)
Schedule 6
Schedule 5
Sodium hydroxide (impurity)
Schedule 6
Schedule 5

Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, including amendments.

This safety data sheet complies with the requirements of Regulation (EC) No. 1272/2008.

National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition [NOHSC: 2011 (2003)].

National Occupational Health and Safety Commission's Approved Criteria for Classifying Hazardous Substances [NOHSC:1008 (2004) 3rd Edition].

National Occupational Health and Safety Commission's Exposure Standards for Atmospheric Contaminants in the occupational Environment [NOHSC:1003 (1995)].

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as Dangerous Goods by the criteria of the Australian Dangerous Goods Code (ADG Code) for transport by road or rail.

International inventories

USA (TSCA)	Complies
European Union (EINECS and ELINCS)	Does not Comply
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Does not Comply

China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Does not Comply
New Zealand (NZIoC)	Complies

15.2 Chemical Safety Report

No information available

16. Other information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Muriel Martin Beurel
Supersedes date	11-Dec-2014
Revision date	18-Oct-2016
Version	4
The following sections have been revised:	All sections, There have been changes with regard to classification.

Text of R phrases mentioned in Section 3
R22 - Harmful if swallowed
R35 - Causes severe burns
R36 - Irritating to eyes

R48/22 - Harmful: danger of serious damage to health by prolonged exposure if swallowed

Full text of H-Statements referred to under sections 2 and 3

H302 - Harmful if swallowed
H373 - May cause damage to organs through prolonged or repeated exposure
H314 - Causes severe skin burns and eye damage
H319 - Causes serious eye irritation

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

SDS no. L071
Version 4
Revision date 31-Jul-2017
Supersedes Date: 02-Aug-2016

Safety Data Sheet
L071 Temporary Clay Stabilizer

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name L071 Temporary Clay Stabilizer
Product code L071

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Clay control agent in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards Not classified

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements

Signal word
None

Hazard Statements
This product is not classified as hazardous therefore no (H) hazard statements assigned.

Precautionary statements
This product is not classified as hazardous therefore has no (P) precautionary statements assigned.

-

Contains No hazardous components

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

May cause slight irritation

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

This product does not contain any hazardous ingredients, or ingredients with national workplace exposure limits.

4. First Aid Measures

4.1 First aid measures

Inhalation If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact Wash skin thoroughly with soap and water. Get medical attention if symptoms occur.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
None known.

Hazardous combustion products
Fire or high temperatures create: Thermal decomposition can lead to release of irritating gases and vapors, Nitrogen oxides (NOx), Carbon oxides (COx).

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8. Keep people away from and upwind of spill/leak. If spilled, take caution, as material can cause surfaces to become very slippery.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Absorb with earth, sand or other non-combustible material and transfer to containers for later disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid breathing vapors or mists. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, Strong oxidizing agents
Storage class	Chemical storage.
Packaging materials	Use specially constructed containers only.

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits	The product does not contain any hazardous materials with occupational exposure limits established.

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required. See section 7 for more information

Personal protective equipment

Eye protection	Use eye protection according to EN 166, designed to protect against liquid splashes Safety glasses with side-shields
Hand protection	Wear gloves according to EN 374 resistant to the solvent(s) in use Impervious gloves made of: Nitrile Break through time >480 minutes Glove thickness 0.4 mm or PVC disposable gloves Break through time >480 minutes Glove thickness 0.7 mm Be aware that liquid may penetrate the gloves. Frequent change is advisable.
Respiratory protection	In case of insufficient ventilation wear suitable respiratory equipment Use respirator with

organic vapor protection (A, brown)

Skin and body protection Wear suitable protective clothing Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	No information available
Odor	Mild amine
Color	Clear - Blue
Odor threshold	Not applicable

Property	**Values**	**Remarks**
pH	6.5 - 9.5	
pH @ dilution	No information available	Not applicable
Melting / freezing point	No information available	
Boiling point/range	125 °C / 257 °F	
Flash point	> 98 °C / 208.4 °F	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	0.99 - 1.20	
Bulk density	No information available	
Relative density	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	No information available
Oxidizing properties	No information available

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	No information available

Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

No specific reactivity hazards associated with this product.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation	May cause irritation of respiratory tract.
Eye contact	May cause slight irritation.
Skin contact	Prolonged contact may cause redness and irritation.
Ingestion	Ingestion may cause stomach discomfort.
Unknown acute toxicity	Not applicable.

Sensitization	This product does not contain any components suspected to be sensitizing.
Mutagenic effects	This product does not contain any known or suspected mutagens.
Carcinogenicity	This product does not contain any known or suspected carcinogens.

Reproductive toxicity	This product does not contain any known or suspected reproductive hazards.
Routes of exposure	Ingestion. Skin contact. Eye contact.
Routes of entry	Skin contact. Eye contact.
Specific target organ toxicity - Single exposure	Not classified
Specific target organ toxicity - Repeated exposure	Not classified.
Aspiration hazard	Not classified.
Other information	Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

12.2 Persistence and degradability

Product is biodegradable.

12.3 Bioaccumulative potential

No product level data available.

12.4 Mobility

Mobility
Soluble in water.

Mobility in soil
After release, adsorbs onto soil.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard

Marine pollutant
No

14.6 Special precautions
None

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	02-Aug-2016
Revision date	31-Jul-2017
Version	4
This SDS has been revised in the following section(s)	1, 2, 3, 5, 7, 8, 9, 11, 15, 16 Updated according to GHS/CLP. No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

Training Advice
It is a good industrial hygiene practice to minimize skin contact

HMIS classification

Health	1
Flammability	1
Physical hazard	0
PPE	B

Disclaimer
The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.
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Safety Data Sheet
Myacide® GA 25

1. Identification

Product identifier used on the label

Myacide® GA 25

Recommended use of the chemical and restriction on use
Recommended use*: Approved only for uses listed on the FIFRA label.

* The “Recommended use” identified for this product is provided solely to comply with a Federal requirement and is not part of the seller's published specification. The terms of this Safety Data Sheet (SDS) do not create or infer any warranty, express or implied, including by incorporation into or reference in the seller's sales agreement.

Details of the supplier of the safety data sheet

Company:
BASF CORPORATION
100 Park Avenue
Florham Park, NJ 07932, USA

Telephone: +1 973 245-6000

Emergency telephone number

CHEMTREC: 1-800-424-9300
BASF HOTLINE: 1-800-832-HELP (4357)

Other means of identification

Substance number:	145849
EPA Registration number:	33753-26
Molecular formula:	CHO(CH2)3CHO
Chemical family:	dialdehydes, aqueous solution
Synonyms:	GLUTARALDEHYDE

2. Hazards Identification

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

Classification of the product

Acute Tox.	4 (oral)	Acute toxicity
Acute Tox.	4 (Inhalation - mist)	Acute toxicity
Skin Corr./Irrit.	1B	Skin corrosion/irritation
Eye Dam./Irrit.	1	Serious eye damage/eye irritation
Resp. Sens.	1	Respiratory sensitization

Skin Sens.	1A	Skin sensitization
STOT SE	3 (irritating to respiratory system)	Specific target organ toxicity — single exposure
Aquatic Chronic	2	Hazardous to the aquatic environment - chronic
Aquatic Acute	1	Hazardous to the aquatic environment - acute

Label elements

Pictogram:



Signal Word:
Danger

Hazard Statement:

H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317	May cause an allergic skin reaction.
H335	May cause respiratory irritation.
H314	Causes severe skin burns and eye damage.
H302 + H332	Harmful if swallowed or if inhaled
H411	Toxic to aquatic life with long lasting effects.
H400	Very toxic to aquatic life.

Precautionary Statements (Prevention):

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P271	Use only outdoors or in a well-ventilated area.
P260	Do not breathe dust/mist/vapours.
P273	Avoid release to the environment.
P284	In case of inadequate ventilation wear respiratory protection.
P272	Contaminated work clothing should not be allowed out of the workplace.
P270	Do not eat, drink or smoke when using this product.
P264	Wash with plenty of water and soap thoroughly after handling.

Precautionary Statements (Response):

P310	Immediately call a POISON CENTER or doctor/physician.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P303 + P361 + P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
P301 + P330 + P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P362 + P364	Take off contaminated clothing and wash it before reuse.
P391	Collect spillage.

Precautionary Statements (Storage):

P403 + P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.

Precautionary Statements (Disposal):

P501	Dispose of contents/container in accordance with local regulations.

Hazards not otherwise classified

No specific dangers known, if the regulations/notes for storage and handling are considered.

Labeling of special preparations (GHS):
Corrosive to the respiratory tract.

3. Composition / Information on Ingredients

According to Regulation 2012 OSHA Hazard Communication Standard; 29 CFR Part 1910.1200

CAS Number	Weight %	Chemical name
111-30-8	>= 20.0 - < 50.0%	glutaral
67-56-1	>= 0.0 - < 0.3%	Methanol

4. First-Aid Measures

Description of first aid measures

General advice:
Immediately remove contaminated clothing. If the patient is likely to become unconscious, place and transport in stable sideways position (recovery position). First aid personnel should pay attention to their own safety.

If inhaled:
Keep patient calm, remove to fresh air, seek medical attention.

If on skin:
Remove contaminated clothing. Rinse skin immediately with plenty of water for 15 - 20 minutes. Seek medical attention. Consult a skin specialist.

If in eyes:
Immediately wash affected eyes for at least 15 minutes under running water with eyelids held open, consult an eye specialist.

If swallowed:
Immediately rinse mouth and then drink plenty of water, do not induce vomiting, seek medical attention.

Most important symptoms and effects, both acute and delayed

Symptoms: The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Further symptoms and / or effects are not known so far
Hazards: No applicable information available.

Indication of any immediate medical attention and special treatment needed

Note to physician

Treatment:	Treat according to symptoms (decontamination, vital functions), no known specific antidote, administer corticosteroid dose aerosol to prevent pulmonary odema.

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media:
water spray, dry powder, foam

Special hazards arising from the substance or mixture

Hazards during fire-fighting:
harmful vapours
Evolution of fumes/fog. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Protective equipment for fire-fighting:
Wear a self-contained breathing apparatus in confined areas or when exposed to combustion products.

Further information:
Contaminated extinguishing water must be disposed of in accordance with official regulations.

Impact Sensitivity:

Impact Weight:	10 kg
Height of Fall:	0.4 m
Method:	Explosive properties
Remarks:	Substance/product is not impact sensitve at room temperature.

6. Accidental release measures

Further accidental release measures:
Pack in tightly closed containers for disposal.

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Pick up with absorbent material (e.g. sand, sawdust, general-purpose binder).
Dispose of absorbed material in accordance with regulations.
For large amounts: Pump off product.
Spills should be contained, solidified, and placed in suitable containers for disposal.

7. Handling and Storage

Precautions for safe handling

No special measures necessary provided product is used correctly.

Protection against fire and explosion:
No special precautions necessary.

Conditions for safe storage, including any incompatibilities

Segregate from foods and animal feeds.

Further information on storage conditions: Keep container tightly closed and in a cool place. Store protected against freezing.

8. Exposure Controls/Personal Protection

Users of a pesticidal product should refer to the product label for personal protective equipment requirements.

Components with occupational exposure limits

Methanol	OSHA PEL	PEL 200 ppm 260 mg/m3 ; TWA value 200 ppm 260 mg/m3 ; SKIN_FINAL ; The substance can be absorbed through the skin. STEL value 250 ppm 325 mg/m3 ;
	ACGIH TLV	TWA value 200 ppm ; STEL value 250 ppm ; Skin Designation ; The substance can be absorbed through the skin.
glutaral	OSHA PEL	CLV 0.2 ppm 0.8 mg/m3 ;
	ACGIH TLV	CLV 0.05 ppm ;

Advice on system design:
Provide local exhaust ventilation to control vapours/mists.

Personal protective equipment

RECOMMENDATIONS FOR MANUFACTURING, COMMERCIAL BLENDING, AND PACKAGING WORKERS:

Respiratory protection:
Wear respiratory protection if ventilation is inadequate. Respiratory protection in case of vapour/aerosol release. Wear a NIOSH-certified (or equivalent) organic vapour/particulate respirator.

Hand protection:
Wear chemical resistant protective gloves.

Eye protection:
Tightly fitting safety goggles (chemical goggles) and face shield.

Body protection:
Body protection must be chosen based on level of activity and exposure., Protective coverall and/or impermeable apron and boots as necessary.

General safety and hygiene measures:
Handle in accordance with good industrial hygiene and safety practice. Wearing of closed work clothing is required additionally to the stated personal protection equipment. Keep away from food, drink and animal feeding stuffs. Avoid contact with skin and eyes. Remove contaminated clothing. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Form:	liquid
Odour:	characteristic

Odour threshold:	No applicable information available.	
Colour:	yellow	
pH value:	5.9 (0.5 %(m), 23 °C)	
Freezing point:	approx. -5 °C (1 ATM)	
Boiling point:	> 100 °C (1 ATM)	
Sublimation point:	No applicable information available.	
Flash point:	not applicable	
Flammability:	No applicable information available.	
Lower explosion limit:	No applicable information available.	
Upper explosion limit:	No applicable information available.	
Autoignition:	> 275 °C	(DIN 51794)
Vapour pressure:	approx. 17.5 mmHg (20 °C) The product has not been tested. The statement has been derived from the properties of the individual components.	
Density:	1.06 g/cm3 (20 °C)	
Relative density:	1.06 (20 °C)	
Vapour density:	No applicable information available.	
Partitioning coefficient n-octanol/water (log Pow):	No applicable information available.	
Thermal decomposition:	No decomposition if correctly stored and handled.	
Viscosity, dynamic:	No applicable information available.	
Viscosity, kinematic:	No applicable information available.	
Solubility in water:	soluble	
Solubility (quantitative):	No applicable information available.	
Solubility (qualitative):	No applicable information available.	
Molar mass:	100 g/mol	
Evaporation rate:	Value can be approximated from Henry's Law Constant or vapor pressure.	
Other Information:	If necessary, information on other physical and chemical parameters is indicated in this section.	

10. Stability and Reactivity

Reactivity
No hazardous reactions if stored and handled as prescribed/indicated.

Corrosion to metals:
No corrosive effect on metal.

Formation of flammable gases:	Remarks:	Forms no flammable gases in the presence of water.

Chemical stability
The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions
The product is chemically stable.

Conditions to avoid
No conditions to avoid anticipated.

Incompatible materials
acids, bases, amines

Hazardous decomposition products

Decomposition products:
Hazardous decomposition products:
carbon monoxide, carbon dioxide

Thermal decomposition:
No decomposition if correctly stored and handled.

11. Toxicological information

Primary routes of exposure

Routes of entry for solids and liquids are ingestion and inhalation, but may include eye or skin contact. Routes of entry for gases include inhalation and eye contact. Skin contact may be a route of entry for liquefied gases.

Acute Toxicity/Effects

Acute toxicity
Assessment of acute toxicity: Of moderate toxicity after single ingestion. Of moderate toxicity after short-term inhalation. Of low toxicity after short-term skin contact.

Oral
Type of value: ATE
Value: 301 mg/kg

Tested as a preparation.

Information on: glutaral
Type of value: LD50
Species: rat (female)
Value: approx. 77 mg/kg (similar to OECD guideline 401)

Information on: Methanol
Type of value: LD50
Species: rat
Value: > 1187 - 2769 mg/kg (BASF-Test)

Inhalation
Type of value: ATE
Value: 1.09 mg/l
Determined for mist

Dermal
Type of value: ATE
Value: 3,790 mg/kg

Assessment other acute effects
Assessment of STOT single:

Causes temporary irritation of the respiratory tract.

Irritation / corrosion
Assessment of irritating effects: Corrosive! Damages skin and eyes.

Skin

Information on: glutaral
Species: rabbit
Result: Corrosive.
Method: similar to OECD guideline 404

Eye

Information on: glutaral
Species: rabbit
Result: Risk of serious damage to eyes.
Method: Draize test

Sensitization
Assessment of sensitization: The substance may cause sensitization of the respiratory tract.
Sensitization after skin contact possible.

Information on: glutaral
Open epicutaneous test (OET)
Species: guinea pig
Result: sensitizing

Species: human
Result: sensitizing

Aspiration Hazard
No aspiration hazard expected.

Chronic Toxicity/Effects

Repeated dose toxicity

Information on: glutaral
Assessment of repeated dose toxicity: After repeated exposure the prominent effect is local irritation. The substance may cause damage to the upper respiratory tract after repeated inhalation, as shown in animal studies.

Genetic toxicity

Information on: glutaral
Assessment of mutagenicity: The substance was mutagenic in various test systems with bacterias and cell cultures; however, these results could not be confirmed in tests with mammals.

Carcinogenicity

Assessment of carcinogenicity: None of the components in this product at concentrations greater than 0.1% are listed by IARC; NTP, OSHA or ACGIH as a carcinogen.

Reproductive toxicity

Information on: glutaral
Assessment of reproduction toxicity: The results of animal studies gave no indication of a fertility impairing effect.

Teratogenicity

Information on: glutaral
Assessment of teratogenicity: No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Other Information
The product has not been tested. The statement has been derived from the properties of the individual components.

Symptoms of Exposure

The most important known symptoms and effects are described in the labelling (see section 2) and/or in section 11., Further symptoms and / or effects are not known so far

Medical conditions aggravated by overexposure
Contact may aggravate pulmonary disorders.

12. Ecological Information

Toxicity

Aquatic toxicity
Assessment of aquatic toxicity:
Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.
The ecological data given are those of the active ingredient.

Toxicity to fish
LC50 (96 h) 0.8 mg/l, Salmo gairdneri, syn. O. mykiss (Fish test acute, static)
The details of the toxic effect relate to the nominal concentration.

LC50 (96 h) 6.2 mg/l, Cyprinodon variegatus (Fish test acute, static)
The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates
EC50 (48 h) 2.1 mg/l, Daphnia magna (Daphnia test acute, static)
The details of the toxic effect relate to the nominal concentration.

EC50 (96 h) 0.78 mg/l, Crassostrea virginica (OPP 72-3 (EPA-Guideline), Flow through.)
The statement of the toxic effect relates to the analytically determined concentration.

Aquatic plants
EC50 (72 h) 0.6 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static)
The statement of the toxic effect relates to the analytically determined concentration.

No observed effect concentration (72 h) 0.025 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static)
The statement of the toxic effect relates to the analytically determined concentration.

EC50 (72 h) 0.92 mg/l (growth rate), Skeletonema costatum (ISO/DIS 10253, static)
The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to fish
No observed effect concentration (97 d) 1.6 mg/l, Oncorhynchus mykiss (Flow through.)
The details of the toxic effect relate to the nominal concentration.

Chronic toxicity to aquatic invertebrates
No observed effect concentration (21 d) 5.0 mg/l, Daphnia magna (OECD Guideline 211, semistatic)

Assessment of terrestrial toxicity
Toxic effects have been observed in studies with terrestric plants. Toxic effects have been observed in studies with soil living organisms.

Soil living organisms

Toxicity to soil dwelling organisms:
LC50 (14 d) 170 mg/kg, Eisenia foetida (OECD Guideline 207, artificial soil)
The details of the toxic effect relate to the nominal concentration.

EC10 (28 d) 10.45 mg/kg, soil dwelling microorganisms (OECD 217, natural soil)
The details of the toxic effect relate to the nominal concentration.

Toxicity to terrestrial plants

EC20 (19 d) 441 mg/kg, Vicia sativa (OECD Guideline 208)

Other terrestrial non-mammals
LD50 (14 d) 206 mg/kg, Anas platyrhynchos (other)

Microorganisms/Effect on activated sludge

Toxicity to microorganisms
OECD Guideline 209 aerobic
activated sludge, domestic/EC20 (30 min): approx. 15 mg/l
The details of the toxic effect relate to the nominal concentration.

Persistence and degradability

Assessment biodegradation and elimination (H2O)
Readily biodegradable (according to OECD criteria).

Elimination information

90 - 100 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Assessment biodegradation and elimination (H2O)

Information on: glutaral

Readily biodegradable (according to OECD criteria).

Elimination information

Information on: glutaral
90 - 100 % DOC reduction (28 d) (OECD 301 A (new version)) (aerobic, activated sludge, domestic)

Assessment of stability in water
In contact with water the substance will hydrolyse slowly.

Information on Stability in Water (Hydrolysis)
$t_{1/2}$ > 1 a (50 °C), (Directive 92/69/EEC, C.7, pH 7)
In contact with water the substance will hydrolyse slowly.

Assessment of stability in water

Information on: glutaral

In contact with water the substance will hydrolyse slowly.

Bioaccumulative potential

Assessment bioaccumulation potential
No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Bioaccumulation potential
Because of the n-octanol/water distribution coefficient (log Pow) accumulation in organisms is not to be expected.

Assessment bioaccumulation potential

Information on: glutaral

No significant accumulation in organisms is expected as a result of the distribution coefficient of n-octanol/water (log Pow).

Mobility in soil

Assessment transport between environmental compartments
The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is possible.

Information on: glutaral

The substance will not evaporate into the atmosphere from the water surface.
Adsorption to solid soil phase is possible.

Additional information

Other ecotoxicological advice:
Data refer to a diluted aqueous solution of the substance.

13. Disposal considerations

Waste disposal of substance:

Dispose of in accordance with national, state and local regulations. It is the waste generator's responsibility to determine if a particular waste is hazardous under RCRA.

Container disposal:
Dispose of in a licensed facility. Recommend crushing, puncturing or other means to prevent unauthorized use of used containers.

RCRA:
This product meets the D002 (characteristic corrosivity) criteria.

14. Transport Information

Land transport
USDOT

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8, EHSM
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

Sea transport
IMDG

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8, EHSM
Marine pollutant:	YES
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

Air transport
IATA/ICAO

Hazard class:	8
Packing group:	II
ID number:	UN 3265
Hazard label:	8
Proper shipping name:	CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (contains GLUTARALDEHYDE)

15. Regulatory Information

Federal Regulations

Registration status:

Biocide	TSCA, US	released / exempt

EPCRA 311/312 (Hazard categories): Refer to SDS section 2 for GHS hazard classes applicable for this product.

State regulations

State RTK	CAS Number	Chemical name
NJ	111-30-8	glutaral
PA	111-30-8	glutaral

Safe Drinking Water & Toxic Enforcement Act, CA Prop. 65:

WARNING: This product can expose you to chemicals including METHANOL, which is known to the State of California to cause birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

NFPA Hazard codes:
Health: 3 Fire: 1 Reactivity: 0 Special:

HMIS III rating
Health: 3 Flammability: 1 Physical hazard: 0

Labeling requirements under FIFRA

This chemical is a pesticide product registered by the Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets, and workplace labels of non-pesticide chemicals. Following is the hazard information as required on the pesticide label.

DANGER:
CORROSIVE.
CAUSES IRREVERSIBLE EYE DAMAGE.
CAUSES SKIN IRRITATION.
HARMFUL IF INHALED.
HARMFUL IF SWALLOWED.
HARMFUL IF ABSORBED THROUGH SKIN.
MAY CAUSE ALLERGIC SKIN REACTION.
CAUSES ASTHMATIC SIGNS AND SYMPTOMS IN HYPER-REACTIVE INDIVIDUALS.
Do not get in eyes, on skin, or on clothing.
Avoid inhalation of vapour.
Not to be used as an aerosol.
Do not swallow.
Wear protective eyeware (goggles or face shield).
Wear chemical resistant protective gloves.
Wear protective clothing.
Wash with plenty of water and soap thoroughly after handling.
Remove contaminated clothing immediately and clean before re-use or dispose it if necessary.

16. Other Information

SDS Prepared by:
BASF NA Product Regulations
SDS Prepared on: 2018/08/31

We support worldwide Responsible Care® initiatives. We value the health and safety of our employees, customers, suppliers and neighbors, and the protection of the environment. Our commitment to Responsible Care is integral to conducting our business and operating our facilities in a safe and environmentally responsible fashion, supporting our customers and suppliers in ensuring the safe and environmentally sound handling of our products, and minimizing the impact of our

operations on society and the environment during production, storage, transport, use and disposal of our products.

Myacide® GA 25 is a registered trademark of BASF Corporation or BASF SE
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END OF DATA SHEET

SDS no. S100
Version 8
Revision date 05-Oct-2020
Supersedes Date: 08-Sep-2017

Safety Data Sheet
Sand S100

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Sand S100
Product code S100

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a fracturing additive in oilfield applications

Uses advised against Consumer use

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Specific target organ toxicity - Repeated exposure	Category 2

Environmental hazards Not classified

Physical Hazards Not classified

2.2 Label elements



Signal word
WARNING

Hazard Statements
H373 - May cause damage to organs through prolonged or repeated exposure

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P314 - Get medical advice/attention if you feel unwell
P501 - Dispose of contents/container to industrial incineration plant

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Contains
Quartz, Crystalline silica

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. NON-DANGEROUS GOODS.

3. Composition/information on Ingredients

3.1 Substances

Chemical Name	EC No	CAS No	Weight-%
Quartz, Crystalline silica	238-878-4	14808-60-7	60-100

3.2 Mixtures

Not applicable

Comments
This product contains a small quantity of quartz, crystalline silica. Prolonged and repeated exposure to concentrations of crystalline silica exceeding the workplace exposure limit (WEL) may lead to chronic lung disease such as silicosis.

4. First Aid Measures

4.1 First aid measures

Inhalation — If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.

Ingestion — Rinse mouth. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person. Get medical attention if symptoms occur.

Skin contact — Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes. Seek medical attention if irritation occurs.

Eye Contact Promptly wash eyes with lots of water while lifting eye lids. Remove contact lenses, if worn. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

4.2. Most important symptoms and effects, both acute and delayed

General advice The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.

Symptoms

Inhalation Please see Section 11. Toxicological Information for further information.

Ingestion Please see Section 11. Toxicological Information for further information.

Skin contact Please see Section 11. Toxicological Information for further information.

Eye contact Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Use extinguishing media appropriate for surrounding material.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
React with hydrofluoric acid (HF) forming toxic gas (SiF4).

Hazardous combustion products
Thermal decomposition can lead to release of irritating gases and vapors

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up
Vacuum up. Avoid generating dust. Put into suitable containers for disposal. After cleaning, flush away traces with water.

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin and eyes. Avoid dust formation. Do not breathe dust. For personal protection see section 8.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. When using do not smoke, eat or drink. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions Provide appropriate exhaust ventilation at places where dust is formed. Keep airborne concentrations below exposure limits.

Storage precautions Keep containers tightly closed in a dry, cool and well-ventilated place Store away from incompatibles, React with hydrofluoric acid (HF) forming toxic gas (SiF4) Strong oxidizing agents

Storage class Chemical storage.

Packaging materials Use specially constructed containers only. Bag with moisture barrier Paper bag (minimum 3 ply), or other industrial container designed for powders and granulated materials

8. Exposure Controls/Personal Protection

8.1 Control parameters

Exposure limits No biological limit allocated

Component Information

Chemical Name	Arabic	Australia	Egypt
Quartz, Crystalline silica	0.1 mg/m³ TWA	0.1mg/m³TWArespirable dust	Not determined
Chemical Name	**India**	**Indonesian**	**Japan**
Quartz, Crystalline silica	Not determined	0.1 mg/m³ TWA	0.03 mg/m³ OEL
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Quartz, Crystalline silica	1 mg/m³ MAC	0.1 mg/m³ TWA	0.1 mg/m³ TWA Confirmed carcinogen
Chemical Name	**Malaysia**	**Philippines**	**Russia**

Quartz, Crystalline silica	0.1 mg/m³ TWA	Not determined	3 mg/m³ STEL 1 mg/m³ TWA Fibrogenic substance 1177, 1178
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Quartz, Crystalline silica	0.025 mg/m³ TWA	Not determined	Not determined

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Provide appropriate exhaust ventilation at places where dust is formed

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against dusts Safety glasses with side-shields Tightly fitting safety goggles

Hand protection Wear gloves according to EN 374 to protect against skin effects from powders Repeated or prolonged contact Use protective gloves made of: Nitrile Neoprene gloves Frequent change is advisable

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Suitable mask with particle filter P3 (European Norm 143) At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before eating, drinking or smoking Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state Solid
Appearance Granules
Odor Odorless
Color Tan
Odor threshold Not applicable

Property	Values	Remarks
pH	Not applicable	
pH @ dilution	No information available	
Melting / freezing point	> 1700 °C / 3092 °F	
Boiling point/range	No information available	

Flash point	Not applicable	
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	Not applicable	
Specific gravity	2.6	@20 °C
Bulk density	1100 - 1600 kg/m³	
Relative density	No information available	
Water solubility	Insoluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	No information available	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	No information available	
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

React with hydrofluoric acid (HF) forming toxic gas (SiF4).

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid dust formation.

10.5 Incompatible materials

Hydrofluoric acid (HF). Strong oxidizing agents.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Inhalation Inhalation of dust may cause shortness of breath, tightness of the chest, a sore throat and cough. May cause respiratory irritation. Repeated or prolonged inhalation of crystalline silica dust can cause delayed lung injury, and other diseases, including silicosis and lung cancer.

Eye contact Dust may cause mechanical irritation.

Skin contact Repeated exposure may cause skin dryness or cracking.

Ingestion Ingestion may cause stomach discomfort.

Unknown acute toxicity Not applicable.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Quartz, Crystalline silica	No data available	No data available	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity Contains a known or suspected carcinogen. Crystalline silica dust is listed by IARC in Group 1 as known to cause lung cancer in humans, if inhaled.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of Exposure Inhalation. Skin contact. Eye contact.

Routes of entry Inhalation.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Category 2.

Target organ effects Respiratory system. Lungs.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Toxicity to algae
This product is not considered toxic to algae.

Toxicity to fish
This product is not considered toxic to fish.

Toxicity to daphnia and other aquatic invertebrates
This product is not considered toxic to invertebrates.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Quartz, Crystalline silica	No information available	No information available	No information available

12.2 Persistence and degradability

See component information below.

Chemical Name	Persistence and degradability
Quartz, Crystalline silica	Inorganic compound

12.3 Bioaccumulative potential

See component information below.

Chemical Name	Bioaccumulation
Quartz, Crystalline silica	Product/Substance is inorganic

12.4 Mobility

Mobility
The product is insoluble and sinks in water. See component information below.

Chemical Name	Mobility
Quartz, Crystalline silica	Insoluble in water

Mobility in soil
See component information below.

Chemical Name	Mobility in soil
Quartz, Crystalline silica	Not expected to adsorb on soil

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information

Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products Dispose of in accordance with local regulations.

Contaminated packaging Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number
Not regulated

14.2. UN proper shipping name
The product is not covered by international regulation on the transport of dangerous goods

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	Not regulated
IMDG/ANTAQ Hazard class	Not regulated
ICAO/ANAC Hazard class/division	Not regulated

14.4 Packing group

ADR/RID/ADN/ADG Packing group	Not regulated
IMDG/ANTAQ Packing group	Not regulated
ICAO/ANAC Packing group	Not regulated

14.5 Environmental hazard
No

14.6 Special precautions
Not applicable

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory Information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

This safety data sheet complies with the requirements of:
The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons
No poisons schedule number allocated

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

Not classified as dangerous goods in accordance with the Australian Code for the Transport of Dangerous Goods by

Road and Rail (ADG)

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Poh Yue Cheong
Supersedes Date:	08-Sep-2017
Revision date	05-Oct-2020
Version	8
This SDS has been revised in the following section(s)	All sections No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	3*
Flammability	0
Physical hazard	0
PPE	E

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SDS no. U028
Version 5
Revision date 08-Jun-2018
Supersedes Date: 03-Jun-2014

Safety Data Sheet
Gelling Agent U28 - 30% Active

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name Gelling Agent U28 - 30% Active
Product code U028

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Used as a gelling agent in oilfield applications

Uses advised against No information available

1.3 Details of the supplier of the safety data sheet

Supplier
Schlumberger Oilfield Australia Pty Ltd
ABN: 74 002 459 225
ACN: 002 459 225
256 St. Georges Terrace, Perth WA 6000
+47 5157 7424

SDS@slb.com

1.4 Emergency Telephone Number

Emergency telephone - (24 Hour) Australia +61 2801 44558, Asia Pacific +65 3158 1074, China +86 10 5100 3039, Europe +44 (0) 1235 239 670, Middle East and Africa +44 (0) 1235 239 671, New Zealand +64 9929 1483, USA 001 281 595 3518

2. Hazards Identification

2.1 Classification of the substance or mixture

GHS Classification

Health hazards

Skin corrosion/irritation	Category 1 Subcategory 1A

Environmental hazards Not classified

Physical Hazards

Substances/mixtures corrosive to metal	Category 1

2.2 Label elements



Signal word
DANGER

Hazard Statements
H314 - Causes severe skin burns and eye damage
H290 - May be corrosive to metals

Precautionary statements
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P280 - Wear protective gloves and eye/face protection
P301 + P330 + P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting
P303 + P361 + P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

Supplementary precautionary statements
P234 - Keep only in original container
P264 - Wash face, hands and any exposed skin thoroughly after handling
P363 - Wash contaminated clothing before reuse
P310 - Immediately call a POISON CENTER or doctor/physician
P390 - Absorb spillage to prevent material damage
P220 - Keep/Store away from combustible materials

Sodium hydroxide

2.3 Other hazards

Not classified as PBT/vPvB by current EU criteria

Australian statement of hazardous/dangerous nature
Classified as Hazardous according to the criteria of NOHSC.
HAZARDOUS SUBSTANCE. DANGEROUS GOODS.

3. Composition/information on ingredients

3.1 Substances

Not applicable

3.2 Mixtures

Chemical Name	EC No	CAS No	Weight-%
Sodium hydroxide	215-185-5	1310-73-2	30

Comments
The product contains other ingredients which do not contribute to the overall classification.

4. First Aid Measures

4.1 First aid measures

Inhalation	If inhaled, remove from area to fresh air. Get medical attention if respiratory irritation develops or if breathing becomes difficult.
Ingestion	Do NOT induce vomiting. Rinse mouth. Risk of product entering the lungs on vomiting after ingestion. Never give anything by mouth to an unconscious person. Immediate medical attention is required.
Skin contact	Promptly wash contaminated skin with soap or mild detergent and water. Promptly remove clothing if soaked through and wash as above. Burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Chemical burns must be treated by a physician.
Eye Contact	Get immediate medical attention. Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye.

4.2. Most important symptoms and effects, both acute and delayed

General advice	Seek medical attention for all burns, regardless how minor they may seem. The severity of the symptoms described will vary dependant of the concentration and the length of exposure. If adverse symptoms develop, the casualty should be transferred to hospital as soon as possible.
Symptoms	
Inhalation	Please see Section 11. Toxicological Information for further information.
Ingestion	Please see Section 11. Toxicological Information for further information.
Skin contact	Please see Section 11. Toxicological Information for further information.
Eye contact	Please see Section 11. Toxicological Information for further information.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

5. Fire-Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media
Water Fog, Alcohol Foam, CO_2, Dry Chemical.

Extinguishing media which must not be used for safety reasons
None known.

5.2. Special hazards arising from the substance or mixture

Unusual fire and explosion hazards
Contact with metals may evolve flammable hydrogen gas.

Hazardous combustion products
Fire or high temperatures create: Heating or fire can release toxic gas.

5.3 Advice for firefighters

Special protective equipment for fire-fighters
As in any fire, wear self-contained breathing apparatus and full protective gear.

Special Fire-Fighting Procedures
Containers close to fire should be removed immediately or cooled with water.

Hazchem code ADG 2R

6. Accidental Release Measures

6.1. Personal precautions, protective equipment and emergency procedures

Do not get on skin or clothing. Wash thoroughly after handling. Do not breathe vapors or spray mist. Use personal protective equipment. See also section 8.

6.2 Environmental precautions

The product should not be allowed to enter drains, water courses or the soil.

Environmental exposure controls
Avoid release to the environment. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for containment
Prevent further leakage or spillage if safe to do so. Dike far ahead of liquid spill for later disposal.

Methods for cleaning up
Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations (see Section 13).

6.4 Reference to other sections

See section 13 for more information.

7. Handling and Storage

7.1 Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Do not get in eyes, on skin or on clothing. Do not breathe vapors or spray mist. Avoid spills and splashing during use.

Hygiene Measures
Use good work and personal hygiene practices to avoid exposure. Wash hands and face before breaks and immediately after handling the product Remove contaminated clothing Do not eat, drink or smoke when using this product

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/precautions	Ensure adequate ventilation. Keep airborne concentrations below exposure limits.
Storage precautions	Keep containers tightly closed in a dry, cool and well-ventilated place Store between 15-25 deg. C (59-77 deg. F) Avoid extreme temperatures Store away from incompatibles, Strong acids Halogenated compounds Metals
Storage class	Corrosive storage.
Packaging materials	High density polyethylene (HDPE) drum or can

8. Exposure controls/personal protection

8.1 Control parameters

Exposure limits Because this product is a liquid, the dust-related Workplace Exposure Limits for the components do not apply.

, Component Information

Chemical Name	Arabic	Australia	Egypt
Sodium hydroxide	Not determined	2 mg/m³ Peak	2 mg/m³ Ceiling
Chemical Name	**India**	**Indonesian**	**Japan**
Sodium hydroxide	2 mg/m³ Ceiling	2 mg/m³ Ceiling	Not determined
Chemical Name	**Kazakhstan**	**Kuwait**	**New Zealand**
Sodium hydroxide	Not determined	2.0 mg/m³ STEL	2 mg/m³ Ceiling
Chemical Name	**Malaysia**	**Philippines**	**Russia**
Sodium hydroxide	2 mg/m³ Ceiling	2 mg/m³ TWA	Not determined
Chemical Name	**Thailand**	**Vietnam**	**Turkey**
Sodium hydroxide	2 mg/m³ TWA	Not determined	Not determined

Notes
No biological limit allocated

8.2 Exposure controls

All chemical Personal Protective Equipment (PPE) should be selected based on an assessment of both the chemical hazard present and the risk of exposure to those hazards. The PPE recommendations below are based on an assessment of the chemical hazards associated with this product. Where this product is used in a mixture with other products or fluids, additional hazards may be created and as such further assessment of risk may be required. The risk of exposure and need of respiratory protection will vary from workplace to workplace and should be assessed by the user in each situation.

Engineering Controls
Ensure adequate ventilation Mechanical ventilation or local exhaust ventilation is required.

Personal protective equipment

Eye protection Use eye protection according to EN 166, designed to protect against liquid splashes Tightly fitting safety goggles / Face-shield

Hand protection Wear chemically resistant gloves (tested to EN 374) in combination with 'basic' employee training Wear protective nitrile rubber gloves
Break through time >480 minutes
Glove thickness 0.35-0.4 mm
Be aware that liquid may penetrate the gloves. Frequent change is advisable.

Respiratory protection In case of insufficient ventilation wear suitable respiratory equipment Respirator with a vapor filter (EN 141) Chemical respirator with inorganic vapour cartridge (Grey B). At work in confined or poorly ventilated spaces, respiratory protection with air supply must be used.

Skin and body protection Wear appropriate personal protective clothing to prevent skin contact Eye wash and emergency shower must be available at the work place.

Hygiene Measures Wash hands before breaks and immediately after handling the product Remove and wash contaminated clothing before re-use



8.2.3 Environmental exposure controls

Environmental exposure	Use appropriate containment to avoid environmental contamination See section 6 for more information

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Appearance	Clear
Odor	Odorless
Color	Colorless
Odor threshold	Not applicable

Property	Values	Remarks
pH	13.5	
pH @ dilution	No information available	
Melting / freezing point	8 °C / 46 °F	
Boiling point/range	115 °C / 239 °F	
Flash point		
Evaporation rate (BuAc =1)	No information available	
Flammability (solid, gas)	Not applicable	
Flammability Limit in Air		
Upper flammability limit	Not applicable	
Lower flammability limit	Not applicable	
Vapor pressure	No information available	
Vapor density	No information available	
Specific gravity	1.3	@20 °C
Bulk density	No information available	
Relative density	No information available	
Water solubility	Soluble in water	
Solubility in other solvents	No information available	
Autoignition temperature	Not applicable	
Decomposition temperature	No information available	
Kinematic viscosity	No information available	
Dynamic viscosity	75 mPa s	@ 20 °C
log Pow	No information available	

Explosive properties	Not applicable
Oxidizing properties	None known.

9.2 Other information

Pour point	No information available
Molecular weight	No information available
VOC content(%)	None
Density	No information available

Comments
The data listed above are typical physical and chemical properties and should not be construed as product specification.

10. Stability and Reactivity

10.1 Reactivity

Corrosive.

10.2 Chemical stability

Stable under normal temperature conditions and recommended use.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization
Hazardous polymerization does not occur.

10.4 Conditions to avoid

Avoid extreme temperatures. Store at ambient conditions.

10.5 Incompatible materials

Strong acids. Halogenated compounds. Metals. Gives off hydrogen by reaction with metals.

10.6 Hazardous decomposition products

See Section 5.2.

11. Toxicological Information

11.1 Information on toxicological effects

Acute toxicity

Product information Causes severe skin burns and eye damage.

Inhalation Inhalation of corrosive fumes/gases may cause coughing, choking, headache, dizziness, and weakness for several hours. Pulmonary edema may occur with tightness in the chest, shortness of breath, bluish skin, decreased blood pressure, and increased heart rate.

Eye contact Causes burns. Causes serious eye damage.

Skin contact Corrosive. Causes burns.

Ingestion Can burn mouth, throat, and stomach.

Toxicology data for the components

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Sodium hydroxide	No data available	1350 mg/kg (Rabbit)	No data available

Sensitization This product does not contain any components suspected to be sensitizing.

Mutagenic effects This product does not contain any known or suspected mutagens.

Carcinogenicity This product does not contain any known or suspected carcinogens.

Reproductive toxicity This product does not contain any known or suspected reproductive hazards.

Routes of exposure Skin contact. Eye contact.

Routes of entry No route of entry noted.

Specific target organ toxicity - Single exposure Not classified

Specific target organ toxicity - Repeated exposure Not classified.

Aspiration hazard Not applicable.

Other information Key literature references and sources for data. See Section 16 for more information.

12. Ecological Information

12.1 Toxicity

The product component(s) are not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
The product may affect the acidity (pH-factor) in water with risk of harmful effects to aquatic organisms.

Toxicity to algae
See component information below.

Toxicity to fish
See component information below.

Toxicity to daphnia and other aquatic invertebrates
See component information below.

Toxicology data for the components

Chemical Name	Toxicity to fish	Toxicity to algae	Toxicity to daphnia and other aquatic invertebrates
Sodium hydroxide	= 45.4 mg/L LC50 Oncorhynchus mykiss 96 h	No information available	No information available

12.2 Persistence and degradability

This product is expected to be readily biodegradable.

12.3 Bioaccumulative potential

Does not bioaccumulate.

12.4 Mobility

Mobility
The product is water soluble, and may spread in water systems.

Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment

Not classified as PBT/vPvB by current EU criteria.

12.6 Other adverse effects.

None known.

12.7 Other information
Key literature references and sources for data. See Section 16 for more information.

13. Disposal considerations

13.1 Waste treatment methods

Waste from residues/unused products	Dispose of as special waste in compliance with local and national regulations.
Contaminated packaging	Empty containers should be taken for local recycling, recovery or waste disposal.

14. Transport information

14.1. UN number

UN/ID No. (ADR/RID/ADN/ADG)	UN1824
UN No. (IMDG/ANTAQ)	UN1824
UN No. (ICAO/ANAC)	UN1824

14.2. UN proper shipping name
SODIUM HYDROXIDE SOLUTION,

14.3 Hazard class(es)

ADR/RID/ADN/ADG Hazard class	8
IMDG/ANTAQ Hazard class	8
ICAO/ANAC Hazard class/division	8

14.4 Packing group

ADR/RID/ADN/ADG Packing group	PG II
IMDG/ANTAQ Packing group	PG II
ICAO/ANAC Packing group	PG II



14.5 Environmental hazard
No

14.6 Special precautions

Hazard identification no (ADR)	80
EmS (IMDG)	F-A, S-B

Emergency Action Code (EAC)	2R
Tunnel restriction code	(E)
Hazchem code ADG	2R

14.7 Transport in bulk according to Annex I/II of MARPOL 73/78 and the IBC Code
Please contact SDS@slb.com for info regarding transport in Bulk.

15. Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The Globally Harmonized System of Classification and Labeling of Chemicals (GHS)

Australian Standard for the Uniform Scheduling of Drugs and Poisons

Sodium hydroxide
Schedule 6
Schedule 5

Safe Work Australia.

Standard for the Uniform Scheduling of Drugs and Poisons (SUSDP).

ADG Code – Australian Dangerous Goods Code

International inventories

USA (TSCA)	Complies
Canada (DSL)	Complies
Philippines (PICCS)	Complies
Japan (ENCS)	Complies
China (IECSC)	Complies
Australia (AICS)	Complies
Korean (KECL)	Complies
New Zealand (NZIoC)	Complies

16. Other Information

Prepared by	Global Regulatory Compliance - Chemicals (GRC - Chemicals) , Ingrid Helland
Supersedes Date:	03-Jun-2014
Revision date	08-Jun-2018
Version	5
This SDS has been revised in the following section(s)	1, 2, 8, 11, 15, 16 No changes with regard to classification have been made.

Key literature references and sources for data
www.ChemADVISOR.com
Supplier
National Chemical Inventories
National regulatory information
National occupational exposure limits

HMIS classification

Health	3
Flammability	0
Physical hazard	1
PPE	X

Disclaimer

The information contained herein is considered in good faith as reliable of the date issued and is based upon on measurements, tests or data derived from supplier's own study or furnished by others. In providing this SDS information, Supplier makes no express or implied warranties as to the information or product; merchantability or fitness of purpose; any express or implied warranty; or non-infringement of intellectual property rights; and supplier assumes no responsibility for any direct, special or consequential damages, results obtained, or the activities of others. To the maximum extent permitted by law, supplier's warranty obligations and buyer's sole remedies are as stated in separate agreement between the parties.

Appendix E Tier 2 Assessment – Worker

Attachment E - Risk Characterisation Calculations

64742-47-8 Distillates (petroleum), hydrotreated light

Adult worker exposure scenario	Total Internal Dose (mg/kg bw/day)	NOAEL (mg/kg bw/day)	Critical effect	MOE (NOAEL / dosage)	Chemical is of concern? (MOE < 100)
Haliburton Frac Recipes					
Occupational Activity					
Transport and storage	Negligible*	1000	maternal toxicity in rats		No
Mixing/blending drilling of hydraulic fracturing chemicals	0.810			1235	
Injection of drilling chemicals	Negligible*				
Cleaning and maintenance (hydraulic fracturing)	0.162			6173	
Combined exposure Mixing/blending and cleaning and maintenance	**0.972**			1029	

* In the absence of accidents/incidents, repeated occupational exposures during transport and storage, or during injection of mixed/blended chemicals, are negligible.
Similarly, repeated occupational exposures to the chemical via the transport and storage of drilling muds are negligible (NICNAS 2017)

Worker exposure during mixing/blending of chemicals

Dermal Exposure

$$Ederm = \frac{C \times Dease \times SAderm \times Bderm}{BW}$$ (source Equation 1 - NICNAS 2017)

Ederm	Internal dermal dose of the chemical, mg/kg bw/day	0.06	mg/kg bw/day	
C	concentration of the chemical, %	100%	%	default concentration of 1000 g/L (100%) is used. Assumes the chemical is in its pure form and not diluted with other chemicals (NICNAS 2017)
Dease	external dose estimated by EASE model, mg/cm2/day	0.1	mg/cm2/day	Assuming no PPE, the upper limit value of DEASE, 0.1 mg/cm2/day is used (NICNAS 2017)
SAderm	surface area of exposed skin, cm2	840	cm2	US EPA 2011, NICNAS 2017
Bderm	dermal bioavailability, %	10%	%	NICNAS 2017
BW	body weight, kg bw.	70	kg bw	enHealth 2012, NICNAS 2017

Inhalation Exposure

$$Einh = \frac{Fresp \times C \times Demkg \times Vair \times Binh \times t}{BW}$$ (source Equation 2 - NICNAS 2017)

Einh	Internal inhalation dose of the chemical, mg/kg bw/day	0.750	mg/kg bw/day	
Fresp	respirable/inhalable fraction of the chemical, dimensionless	1	dimensionless	assumed to be 1 (NICNAS 2017)
C	concentration of the chemical, %	100%	%	default concentration of 1000 g/L (100%) is used as the concentration of chemical when delivered to site. Assumes the chemical is in its pure form and not diluted with other chemicals (NICNAS 2017)
Demkg	external dose estimated by EMKG-EXPO-TOOL, mg/m3	0.6	mg/m3	NICNAS 2017
Vair	worker ventilation rate, m3/day	22	m3/day	enHealth 2012, NICNAS 2017
Binh	inhalation bioavailability, %	100%	%	NICNAS 2017
t	duration of exposure, h/day	4	h/day	assumed to be four hours, which is an estimate of the duration of manual handling activities that occur during mixing (NICNAS 2017)
BW	body weight, kg bw	70	kg bw	enHealth 2012, NICNAS 2017
t	time	4	hours	NICNAS 2017

Etotal = Ederm + Einh

Etotal = 0.810 mg/kg bw/day

Worker exposure during cleaning and maintenance (drilling)

Dermal Exposure

$$Ederm = \frac{C \times Dease \times SAderm \times Bderm}{BW}$$

Ederm	Internal dermal dose of the chemical, mg/kg bw/day	0.012	mg/kg bw/day	
C	concentration of the chemical, %	10%	%	a default concentration of 10 g/L (100%) is used as the concentration of chemical in the final formulation prior to injection (NICNAS 2017)
Dease	external dose estimated by EASE model, mg/cm2/day	0.1	mg/cm2/day	Assuming no PPE, the upper limit value of Dease, 0.1 mg/cm2/day, is used (NICNAS 2017).
SAderm	surface area of exposed skin, cm2	840	cm2	for hands (USEPA 2011, NICNAS 2017)
Bderm	dermal bioavailability, %	10%	%	NICNAS 2017
BW	body weight, kg bw.	70	kg bw	enHealth 2012, NICNAS 2017
t	time	8	hours	NICNAS 2017

Inhalation Exposure

$$Einh = \frac{Fresp \times C \times Demkg \times Vair \times Binh \times t}{BW}$$

Einh	Internal inhalation dose of the chemical, mg/kg bw/day	0.150	mg/kg bw/day	
Fresp	respirable/inhalable fraction of the chemical, dimensionless	1	dimensionless	assumed to be 1 (NICNAS 2017)
C	concentration of the chemical, %	10%	%	a default concentration of 10 g/L (100%) is used as the concentration of chemical in the final formulation prior to injection (NICNAS 2017)
Demkg	external dose estimated by EMKG-EXPO-TOOL, mg/m3	0.6	mg/m3	Assuming no PPE, the upper limit value is used - EMKG-EXPO-TOOL, NICNAS
Vair	worker ventilation rate, m3/day	22	m3/day	enHealth 2012, NICNAS 2017
Binh	inhalation bioavailability, %	100%	%	NICNAS 2017
t	duration of exposure, h/day	8	h/day	assued to be eight hours which is an estimate of the manual handling activities that occur during cleaning and maintenance (NICNAS 2017)
BW	body weight, kg bw	70	kg bw	enHealth 2012, NICNAS 2017

Etotal = Ederm + Einh

Etotal = 0.162 mg/kg bw/day

Appendix F Tier 2 Assessment – Avian Wildlife

Table F-1
Tier 2 Assessment - Summary
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Common Name	Scientific Name	Body Mass (Kg)								Drinking WIR (L/day)[3,4]
		Sex[1]	N	Mean	Standard Deviation	Min	Max	Location	Source ID[2]	Mean
Crested Pigeon	*Ocyphaps lophotes*	**B**	**21**	**0.204**	**---**	**0.142**	**0.26**	**Australia**	**515a**	**0.020**
Willie Wagtail	*Rhipidura leucophrys picata*	**B**	**13**	**0.0201**	**---**	**0.0145**	**0.0255**	**Australia**	**518a**	**0.004**
Peaceful Dove	*Geopelia placida*	**B**	**38**	**0.0478**	**---**	**0.035**	**0.065**	**Australia**	**515a**	**0.008**
Cattle Egret	*Bubulcus ibis*	M	27	0.372	---	0.296	0.46	FL, USA	1207	0.0304
Cattle Egret	*Bubulcus ibis*	**F**	**59**	**0.36**	**---**	**0.27**	**0.512**	**FL, USA**	**1207**	**0.0298**
Brown Honeyeater	*Lichmera indistincta*	M	37	0.0118	0.0015	0.009	0.015	Australia	517	0.0030
Brown Honeyeater	*Lichmera indistincta*	**F**	**15**	**0.0106**	**0.0021**	**0.008**	**0.014**	**Australia**	**517**	**0.0028**

Notes:

1, Sex: M, Male; F, Female; B, Both

2, Body mass statistics compiled in Dunning (2008); Original source documents based on Source ID in Dunning (2008) include:

515a, *Higgins, P J and S J J F Davies 1996 Handbook of Australian, New Zealand and Antarctic birds Oxford University Press, Mel-bourne, Australia Volume 3*

518a, *Higgins, P J , J M Peter, and S J Cowling 2006 Handbook of Australian, New Zealand and Antarctic birds Oxford University Press, Melbourne, Australia Volume 7*

1207, *Telfair, R C 1994 Cattle Egret (Bubulcus ibis) In The Birds of North America, A Poole and F Gill (editors) The Birds of North America, Inc , Philadelphia, PA,* and The American Ornithologists' Union, Washington, DC Number 113

517, *Higgins, P J , J M Peter, and W K Steele 2001 Handbook of Australian, New Zealand and Antarctic birds Oxford University Press, Melbourne, Australia Volume 5*

3, Drinking water ingestion rate (WIR) based on the allometric relationship developed by Calder and Braun (1983), where WIR (L/day) = 0.059 x BW $(Kg)^{0.67}$

4, Proposed WIR shown in bold, estimated based on the arithmetic mean of female or combined body mass; WIR may be estimated based on other body mass statistics depending on the appropriate exposure scenario.

kg = kilogram

Table F-2
Tier 2 Assessment - Crested Pigeon
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Avian NOAELt [1]	Avian NOAEL		Avian Receptor	
			Test Animal			Test Animal		Crested Pigeon	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Amine oxides, cocoalkyldimethyl	61788-90-7	42	Rat	0.35	NA	NA	NA	0.204	4.8E+01
Chlorous acid, sodium salt	7758-19-2	4	Rat	0.35	NA	NA	NA	0.204	4.6E+00
Crontonaldehyde	123-73-9	2.5	Rat	0.35	NA	NA	NA	0.204	2.9E+00
Glutaraldehyde	111-30-8	4	Rat	0.35	206	Mallard Duck	1.58	0.204	3.4E+02
Tributyl tetradecyl phosphonium chloride	81741-28-8	8.66	Rat	0.35	1980.0	Bobwhite Quail	0.178	0.204	1.9E+03
Octamethylcyclotetrasiloxane	556-67-2	1000	Rat	0.35	NA	NA	NA	0.204	1.1E+03
Decamethyl cyclopentasiloxane	541-02-6	1000	Rat	0.35	NA	NA	NA	0.204	1.1E+03
Dodecamethylcyclohexasiloxane	540-97-6	1000	Rat	0.35	NA	NA	NA	0.204	1.1E+03
Copper (II) sulfate	7758-98-7	16.7	Rat	0.35	NA	NA	NA	0.204	1.9E+01
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	40.3	Rat	0.35	NA	NA	NA	0.204	4.6E+01

Notes:
NOAELt = No observed adverse effect level test animal
kg = kilogram
NA = not applicable
TRV = toxicity reference value
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ WeightAvian}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.020	Table F-1
	EF	Exposure frequency	day/yr	21	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.204	Table F-1
	AT-NC	Averaging time - noncancer	days	365	BPJ

Notes:
a/ Units:
l/day = litres per day
day/yr = days per year
yr = year
kg = kilogram
b/ References:
BPJ - Best Professional Judgement

Table F-2
Tier 2 Assessment - Crested Pigeon
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	EPC[1]	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	TRVs		Ingestion
Amine oxides, cocoalkyldimethyl	61788-90-7	3.0	4.8E+01	1.7E-02	3.6E-04
Chlorous acid, sodium salt	7758-19-2	0.12	4.6E+00	6.9E-04	1.5E-04
Crontonaldehyde	123-73-9	0.12	2.9E+00	6.9E-04	2.4E-04
Glutaraldehyde	111-30-8	1.00	3.4E+02	5.8E-03	1.7E-05
Tributyl tetradecyl phosphonium chloride	81741-28-8	28.00	1.9E+03	1.6E-01	8.4E-05
Octamethylcyclotetrasiloxane	556-67-2	0.001	1.1E+03	5.7E-06	5.0E-09
Decamethyl cyclopentasiloxane	541-02-6	0.001	1.1E+03	5.7E-06	5.0E-09
Dodecamethylcyclohexasiloxane	540-97-6	0.001	1.1E+03	5.7E-06	5.0E-09
Copper (II) sulfate	7758-98-7	0.001	1.9E+01	5.7E-06	3.0E-07
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.10	4.6E+01	5.7E-04	1.2E-05
				Cumulative:	**8.6E-04**

Notes:
CW = concentration in water
EPC = exposure point concentration
mg/kg/day = milligrams per kilograms per day
mg/l = milligrams per litre
NA = not available/applicable
TRV = toxicity reference value
1/ EPC is injected concentration presented on Tables 1 and 2.

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$

Table F-3
Tier 2 Assessment - Willie Wagtail
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL Test Animal		Avian NOAELt [1]	Avian NOAEL Test Animal		Avian Receptor Willie Wagtail	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Amine oxides, cocoalkyldimethyl	61788-90-7	42	Rat	0.35	NA	NA	NA	0.0201	8.6E+01
Chlorous acid, sodium salt	7758-19-2	4	Rat	0.35	NA	NA	NA	0.0201	8.2E+00
Crontonaldehyde	123-73-9	2.5	Rat	0.35	NA	NA	NA	0.0201	5.1E+00
Glutaraldehyde	111-30-8	4	Rat	0.35	206	Mallard Duck	1.58	0.0201	6.1E+02
Tributyl tetradecyl phosphonium chloride	81741-28-8	8.66	Rat	0.35	1980.0	Bobwhite Quail	0.178	0.0201	3.4E+03
Octamethylcyclotetrasiloxane	556-67-2	1000	Rat	0.35	NA	NA	NA	0.0201	2.0E+03
Decamethyl cyclopentasiloxane	541-02-6	1000	Rat	0.35	NA	NA	NA	0.0201	2.0E+03
Dodecamethylcyclohexasiloxane	540-97-6	1000	Rat	0.35	NA	NA	NA	0.0201	2.0E+03
Copper (II) sulfate	7758-98-7	16.7	Rat	0.35	NA	NA	NA	0.0201	3.4E+01
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	40.3	Rat	0.35	NA	NA	NA	0.0201	8.2E+01

Notes:
NOAELt = No observed adverse effect level test animal
kg = kilogram
NA = not applicable
TRV = toxicity reference value
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ WeightAvian}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.004	Table F-1
	EF	Exposure frequency	day/yr	21	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.0201	Table F-1
	AT-NC	Averaging time - noncancer	days	365	BPJ

Notes:
a/ Units:
l/day = litres per day
day/yr = days per year
yr = year
kg = kilogram
b/ References:
BPJ - Best Professional Judgement

Table F-3
Tier 2 Assessment - Willie Wagtail
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	EPC [1]	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	TRVs		Ingestion
Amine oxides, cocoalkyldimethyl	61788-90-7	3.00	8.6E+01	3.7E-02	4.3E-04
Chlorous acid, sodium salt	7758-19-2	0.12	8.2E+00	1.5E-03	1.8E-04
Crontonaldehyde	123-73-9	0.12	5.1E+00	1.5E-03	2.9E-04
Glutaraldehyde	111-30-8	1.00	6.1E+02	1.2E-02	2.0E-05
Tributyl tetradecyl phosphonium chloride	81741-28-8	28.00	3.4E+03	3.5E-01	1.0E-04
Octamethylcyclotetrasiloxane	556-67-2	0.001	2.0E+03	1.2E-05	6.0E-09
Decamethyl cyclopentasiloxane	541-02-6	0.001	2.0E+03	1.2E-05	6.0E-09
Dodecamethylcyclohexasiloxane	540-97-6	0.001	2.0E+03	1.2E-05	6.0E-09
Copper (II) sulfate	7758-98-7	0.001	3.4E+01	1.2E-05	3.6E-07
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.10	8.2E+01	1.2E-03	1.5E-05
				Cumulative:	**1.0E-03**

Notes:
CW = concentration in water
EPC = exposure point concentration
mg/kg/day = milligrams per kilograms per day
mg/l = milligrams per liter
NA = not available/applicable
TRV = toxicity reference value
1/ EPC is injected concentration presented on Tables 1 and 2.

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$

Table F-4
Tier 2 Assessment - Peaceful Dove
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL Test Animal		Avian NOAELt [1]	Avian NOAEL Test Animal		Avian Receptor Peaceful Dove	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Amine oxides, cocoalkyldimethyl	61788-90-7	42	Rat	0.35	NA	NA	NA	0.0478	6.9E+01
Chlorous acid, sodium salt	7758-19-2	4	Rat	0.35	NA	NA	NA	0.0478	6.6E+00
Crontonaldehyde	123-73-9	2.5	Rat	0.35	NA	NA	NA	0.0478	4.1E+00
Glutaraldehyde	111-30-8	4	Rat	0.35	206	Mallard Duck	1.58	0.0478	4.9E+02
Tributyl tetradecyl phosphonium chloride	81741-28-8	8.66	Rat	0.35	1980.0	Bobwhite Quail	0.178	0.0478	2.8E+03
Octamethylcyclotetrasiloxane	556-67-2	1000	Rat	0.35	NA	NA	NA	0.0478	1.6E+03
Decamethyl cyclopentasiloxane	541-02-6	1000	Rat	0.35	NA	NA	NA	0.0478	1.6E+03
Dodecamethylcyclohexasiloxane	540-97-6	1000	Rat	0.35	NA	NA	NA	0.0478	1.6E+03
Copper (II) sulfate	7758-98-7	16.7	Rat	0.35	NA	NA	NA	0.0478	2.7E+01
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	40.3	Rat	0.35	NA	NA	NA	0.0478	6.6E+01

Notes:
NOAELt = No observed adverse effect level test animal
kg = kilogram
NA = not applicable
TRV = toxicity reference value
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ WeightAvian}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.008	Table F-1
	EF	Exposure frequency	day/yr	21	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.0478	Table F-1
	AT-NC	Averaging time - noncancer	days	365	BPJ

Notes:
a/ Units:
l/day = litres per day
day/yr = days per year
yr = year
kg = kilogram
b/ References:
BPJ - Best Professional Judgement

Table F-4
Tier 2 Assessment - Peaceful Dove
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	EPC [1]	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	TRVs		Ingestion
Amine oxides, cocoalkyldimethyl	61788-90-7	3.00	6.9E+01	2.8E-02	4.0E-04
Chlorous acid, sodium salt	7758-19-2	0.12	6.6E+00	1.1E-03	1.7E-04
Crontonaldehyde	123-73-9	0.12	4.1E+00	1.1E-03	2.7E-04
Glutaraldehyde	111-30-8	1.00	4.9E+02	9.3E-03	1.9E-05
Tributyl tetradecyl phosphonium chloride	81741-28-8	28.00	2.8E+03	2.6E-01	9.4E-05
Octamethylcyclotetrasiloxane	556-67-2	0.001	1.6E+03	9.3E-06	5.6E-09
Decamethyl cyclopentasiloxane	541-02-6	0.001	1.6E+03	9.3E-06	5.6E-09
Dodecamethylcyclohexasiloxane	540-97-6	0.001	1.6E+03	9.3E-06	5.6E-09
Copper (II) sulfate	7758-98-7	0.001	2.7E+01	9.3E-06	3.4E-07
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.10	6.6E+01	9.3E-04	1.4E-05
				Cumulative:	**9.7E-04**

Notes:
CW = concentration in water
EPC = exposure point concentration
mg/kg/day = milligrams per kilograms per day
mg/l = milligrams per liter
NA = not available/applicable
TRV = toxicity reference value
1/ EPC is injected concentration presented on Tables 1 and 2.

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$

Table F-5
Tier 2 Assessment - Cattle Egret
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL		Avian NOAELt [1]	Avian NOAEL		Avian Receptor	
			Test Animal			Test Animal		Cattle Egret	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Amine oxides, cocoalkyldimethyl	61788-90-7	42	Rat	0.35	NA	NA	NA	0.36	4.2E+01
Chlorous acid, sodium salt	7758-19-2	4	Rat	0.35	NA	NA	NA	0.36	4.0E+00
Crontonaldehyde	123-73-9	2.5	Rat	0.35	NA	NA	NA	0.36	2.5E+00
Glutaraldehyde	111-30-8	4	Rat	0.35	206	Mallard Duck	1.58	0.36	3.0E+02
Tributyl tetradecyl phosphonium chloride	81741-28-8	8.66	Rat	0.35	1980.0	Bobwhite Quail	0.178	0.36	1.7E+03
Octamethylcyclotetrasiloxane	556-67-2	1000	Rat	0.35	NA	NA	NA	0.36	9.9E+02
Decamethyl cyclopentasiloxane	541-02-6	1000	Rat	0.35	NA	NA	NA	0.36	9.9E+02
Dodecamethylcyclohexasiloxane	540-97-6	1000	Rat	0.35	NA	NA	NA	0.36	9.9E+02
Copper (II) sulfate	7758-98-7	16.7	Rat	0.35	NA	NA	NA	0.36	1.7E+01
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	40.3	Rat	0.35	NA	NA	NA	0.36	4.0E+01

Notes:
NOAELt = No observed adverse effect level test animal
kg = kilogram
NA = not applicable
TRV = toxicity reference value
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ WeightAvian}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.030	Table F-1
	EF	Exposure frequency	day/yr	21	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.36	Table F-1
	AT-NC	Averaging time - noncancer	days	365	BPJ

Notes:
a/ Units:
l/day = litres per day
day/yr = days per year
yr = year
kg = kilogram
b/ References:
BPJ - Best Professional Judgement

Table F-5
Tier 2 Assessment - Cattle Egret
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	EPC[1]	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	TRVs		Ingestion
Amine oxides, cocoalkyldimethyl	61788-90-7	3.00	4.2E+01	1.4E-02	3.4E-04
Chlorous acid, sodium salt	7758-19-2	0.12	4.0E+00	5.7E-04	1.4E-04
Crontonaldehyde	123-73-9	0.12	2.5E+00	5.7E-04	2.3E-04
Glutaraldehyde	111-30-8	1.0041	3.0E+02	4.8E-03	1.6E-05
Tributyl tetradecyl phosphonium chloride	81741-28-8	28.00	1.7E+03	1.3E-01	8.0E-05
Octamethylcyclotetrasiloxane	556-67-2	0.001	9.9E+02	4.8E-06	4.8E-09
Decamethyl cyclopentasiloxane	541-02-6	0.001	9.9E+02	4.8E-06	4.8E-09
Dodecamethylcyclohexasiloxane	540-97-6	0.001	9.9E+02	4.8E-06	4.8E-09
Copper (II) sulfate	7758-98-7	0.001	1.7E+01	4.8E-06	2.9E-07
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.10	4.0E+01	4.8E-04	1.2E-05
				Cumulative:	**8.2E-04**

Notes:
CW = concentration in water
EPC = exposure point concentration
mg/kg/day = milligrams per kilograms per day
mg/l = milligrams per liter
NA = not available/applicable
TRV = toxicity reference value
1/ EPC is injected concentration presented on Tables 1 and 2.

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$

Table F-6
Tier 2 Assessment - Brown Honeyeater
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	Mammal NOAELt	Mammal NOAEL Test Animal		Avian NOAELt [1]	Avian NOAEL Test Animal		Avian Receptor Brown Honeyeater	
			Animal	Body Weight (kg)		Animal	Body Weight (kg)	Body Weight (kg)	Derived TRV
Amine oxides, cocoalkyldimethyl	61788-90-7	42	Rat	0.35	NA	NA	NA	0.0106	1.0E+02
Chlorous acid, sodium salt	7758-19-2	4	Rat	0.35	NA	NA	NA	0.0106	9.6E+00
Crontonaldehyde	123-73-9	2.5	Rat	0.35	NA	NA	NA	0.0106	6.0E+00
Glutaraldehyde	111-30-8	4	Rat	0.35	206	Mallard Duck	1.58	0.0106	7.2E+02
Tributyl tetradecyl phosphonium chloride	81741-28-8	8.66	Rat	0.35	1980.0	Bobwhite Quail	0.178	0.0106	4.0E+03
Octamethylcyclotetrasiloxane	556-67-2	1000	Rat	0.35	NA	NA	NA	0.0106	2.4E+03
Decamethyl cyclopentasiloxane	541-02-6	1000	Rat	0.35	NA	NA	NA	0.0106	2.4E+03
Dodecamethylcyclohexasiloxane	540-97-6	1000	Rat	0.35	NA	NA	NA	0.0106	2.4E+03
Copper (II) sulfate	7758-98-7	16.7	Rat	0.35	NA	NA	NA	0.0106	4.0E+01
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	40.3	Rat	0.35	NA	NA	NA	0.0106	9.7E+01

Notes:
NOAELt = No observed adverse effect level test animal
kg = kilogram
NA = not applicable
TRV = toxicity reference value
1/ If an avian NOAEL was not available, the mammal NOAEL was used to derive the TRV for the avian receptor.

$$Derived\ TRV = NOAEL_{test} * \left(\frac{Body\ Weighttest}{Body\ WeightAvian}\right)^{(1/4)}$$

Exposure Route	Parameter Code	Parameter Definition	Units (a)	Parameter Value	Source (b)
Ingestion	IR	Ingestion rate	l/day	0.0028	Table F-1
	EF	Exposure frequency	day/yr	21	BPJ
	ED	Exposure duration	yr	1	BPJ
	BW	Body weight	kg	0.0106	Table F-1
	AT-NC	Averaging time - noncancer	days	365	BPJ

Notes:
a/ Units:
l/day = litres per day
day/yr = days per year
yr = year
kg = kilogram
b/ References:
BPJ - Best Professional Judgement

Table F-6
Tier 2 Assessment - Brown Honeyeater
Imperial Oil Gas and Imperial Oil and Gas A Northern Territory Tenement - Chemical Risk Assessment

Constituent Name	CAS No.	EPC [1]	Toxicity	Total Intake (mg/kg/day)	Hazard Quotient
		CW (mg/l)	TRVs		Ingestion
Amine oxides, cocoalkyldimethyl	61788-90-7	3.00	1.0E+02	4.6E-02	4.5E-04
Chlorous acid, sodium salt	7758-19-2	0.12	9.6E+00	1.8E-03	1.9E-04
Crontonaldehyde	123-73-9	0.12	6.0E+00	1.8E-03	3.0E-04
Glutaraldehyde	111-30-8	1.00406	7.2E+02	1.5E-02	2.1E-05
Tributyl tetradecyl phosphonium chloride	81741-28-8	28.00	4.0E+03	4.3E-01	1.1E-04
Octamethylcyclotetrasiloxane	556-67-2	0.001	2.4E+03	1.5E-05	6.3E-09
Decamethyl cyclopentasiloxane	541-02-6	0.001	2.4E+03	1.5E-05	6.3E-09
Dodecamethylcyclohexasiloxane	540-97-6	0.001	2.4E+03	1.5E-05	6.3E-09
Copper (II) sulfate	7758-98-7	0.001	4.0E+01	1.5E-05	3.8E-07
Dicoco dimethyl quaternary ammonium chloride	61789-77-3	0.10	9.7E+01	1.5E-03	1.6E-05
				Cumulative:	**1.1E-03**

Notes:
CW = concentration in water
EPC = exposure point concentration
mg/kg/day = milligrams per kilograms per day
mg/l = milligrams per liter
NA = not available/applicable
TRV = toxicity reference value
1/ EPC is injected concentration presented on Tables 1 and 2.

$$Total\ Intake = \frac{EPC\ \times IR\ \times EF\ \times ED}{BW\ \times ED\ x\ 365\ ^{days}/_{year}}$$

$$Hazard\ Quotient = \frac{Total\ Intake\ \left(\frac{mg}{kg-day}\right)}{TRV\ \left(\frac{mg}{kg-day}\right)}$$